UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

THE CIGNA GROUP, Plaintiff, v. CELGENE CORPORATION and BRISTOL MYERS SQUIBB COMPANY, Defendants.	Civil Action No. 1:25-cv-5237

COMPLAINT AND DEMAND FOR JURY TRIAL

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Plaintiff The Cigna Group ("Cigna") hereby sues Celgene Corporation and Bristol Myers Squibb Company. Cigna alleges, based on personal knowledge of facts known to it, and upon information and belief based on reasonable investigation, as follows.

I. INTRODUCTION

1. This civil action alleges that pharmaceutical giants Bristol Myers and Celgene unlawfully extended, and continue to extend, a monopoly in the market for pomalidomide, a blockbuster drug used in the treatment of multiple myeloma and sold under the brand name Pomalyst. Celgene accomplished the scheme (i) through a pattern of fraud on the U.S. patent office, (ii) by abuse of the federal judicial system, and (iii) by eventually settling with generic competitors for extended delay of generic entry for years through agreements that protect unlawful supra-competitive pricing. As a result, purchasers of this $2.25 billion a year drug—like Cigna—have overpaid, and continue to overpay, for pomalidomide by many hundreds of millions, if not billions, of dollars.

2. *Fraud on the U.S. Patent and Trademark Office.* Celgene sought and obtained method of use patents claiming pomalidomide to treat multiple myeloma, never disclosing to the U.S. Patent and Trademark Office (PTO) that a patent for the same use had already been allowed to another inventor (a doctor at Boston Children's Hospital) years earlier. Celgene was well-aware of these earlier patents and patent applications, which Celgene had worked assiduously to block. Celgene also defrauded the PTO to obtain formulation patents by submitting false expert declarations attesting that, in formulating the capsule containing the Pomalyst active ingredient, Celgene's agents solved for "unexpected" stability issues. This statement was false. It was well known that thalidomide analogs, such as pomalidomide, posed stability issues, which scientists in the field had been addressing through routine optimization for decades. Had the fraud not

occurred, the patents would not have issued, and generic pomalidomide would have been available sooner than it will be.

3. *Abuse of the federal judicial system*. Celgene abused the federal judicial system by filing a series of sham lawsuits. The lawsuits were a sham because no reasonable litigant in Celgene's position would have expected to prevail in showing that the patents at issue (method of treatment, formulation, and crystal form) were both valid and infringed. Celgene obtained the method of treatment patents by fraud, including by failing to disclose that a patent had already been allowed to another inventor for the same claimed invention years earlier. And even if Celgene had not obtained the method of treatment patents by fraud, they were invalid as obvious in light of the prior art. Like the method of treatment patents, Celgene obtained the formulation patents by fraud and they were obvious in light of the prior art. The formulation patents were also exceedingly easy to design around, such that a patent holder in Celgene's position would have had no expectation of prevailing on an argument that the patents were both valid and infringed. Finally, the crystal form patents were invalid, including because they are based on theoretically impossible data. A patent holder in Celgene's position would have no expectation of proving infringement by ANDA products that have a different crystal form than the forms claimed by Celgene's patents. Celgene nonetheless pursued sham litigation to block and delay generic entry. Absent these baseless suits, generic pomalidomide would have reached the market sooner.

4. *Reverse payments to, and market allocation with, would-be competitors*. Knowing they could not prevail in the Pomalyst patent litigation, Celgene, and its new parent Bristol Myers, paid off at least several of the first-to-file generic companies—including Aurobindo, Eugia, Breckenridge, Natco, and Teva—to have each discontinue its challenge to the pomalidomide patents and delay entry into the U.S. market. Celgene/Bristol Myers induced delay of generic

Pomalyst by (among other things) making large reverse payments in linked Revlimid settlements. The Revlimid settlements created a fixed-period output restriction for generic Revlimid from 2022 to January 31, 2026. The output restriction served as a means of delivering a reverse payment, conveying hundreds of millions of dollars in supracompetitive profits to the generics that they could not have made by litigating, prevailing in the patent litigation, and launching, because only an agreement to restrict generic Revlimid could have maintained generic pricing in the $500-$650 per capsule range instead of the ~$50 per capsule that would otherwise have occurred. The output restriction also served as an enforcement mechanism for generic Pomalyst delay because launching prior to January 31, 2026 would have substantially undercut the future cash flows promised by the creation of the output restriction by driving the allocated generic Revlimid market to generic Pomalyst. That the agreed-to date for generic Pomalyst launches is in the "first quarter of 2026"—the exact time the payment mechanism terminated—underscores the linked nature of the Revlimid and Pomalyst agreements. Had Celgene and Bristol Myers not paid off their would-be competitors, generic pomalidomide would have been available sooner than it will be.

5. Taken severally or together, the wrongdoing violated, and continues to violate, the federal Sherman Act. Plaintiff seeks monetary relief in the form of treble damages, and because the effect of the wrongdoing is ongoing, injunctive relief.

II. PARTIES

6. The Cigna Group is a corporation organized under the laws of the State of Delaware, with its principal place of business in Bloomfield, Connecticut, and a principal office location at Two Liberty Plaza located at 1601 Chestnut Street in Philadelphia, Pennsylvania.

7. Cigna is the parent company, or otherwise affiliated/related company, to Accredo Health Group, Inc. ("Accredo"). Accredo buys prescription drugs directly from

manufacturers and wholesalers and dispenses them through its specialty pharmacy to Cigna's and other payers' plan members. Through the ordinary course of its pharmacy business, Accredo has purchased Pomalyst directly from Defendants Celgene and BMS pursuant to contractual agreements. Accredo has assigned its claims related to these purchases to Cigna, who brings these claims on its behalf as its parent company.

8. The defendant Bristol Myers Squibb Company ("Bristol Myers") is a pharmaceutical company organized and existing under the laws of the State of Delaware. During most times relevant to the complaint, Bristol Myers maintained its principal executive offices at 430 E. 29th Street, 14FL, New York, NY 10016. Bristol Myers has since changed its principal executive offices to Route 206 & Province Line Road, Princeton, New Jersey 08543.

9. The defendant Celgene Corporation is a pharmaceutical company organized and existing under the laws of the State of Delaware with a principal place of business at 86 Morris Avenue, Summit, New Jersey 07901. In 2019, Celgene Corporation was acquired by, and became a wholly owned subsidiary of, Bristol Myers. Celgene Corporation, whether before or after its acquisition by Bristol Myers, is referred to as "Celgene."

III. JURISDICTION AND VENUE

10. This Court has jurisdiction over this action pursuant to 15 U.S.C. §§ 15 and 26, and 28 U.S.C. §§ 1331 and 1337. Cigna asserts federal claims for treble damages, injunctive relief, and costs of suit, including reasonable attorneys' fees, against Defendants under Section 2 of the Sherman Act, 15 U.S.C. § 2, and Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26.

11. This Court has personal jurisdiction over Defendants because Defendants are present in the United States, do business in the United States, have registered agents in the United States, may be found in the United States, and are otherwise subject to the service of

process provisions of 15 U.S.C. § 22. Each Defendant has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme and conspiracy throughout the United States, including in this district. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this district.

12. Venue is appropriate within this district under Section 12 of the Clayton Act, 15 U.S.C. §§ 15(a) and 22, and 28 U.S.C. § 1391. During the relevant period, Defendants resided, transacted business, or had agents in this district.

IV. REGULATORY AND ECONOMIC BACKGROUND

A. The regulatory structure for approval and substitution of generic drugs balances new drug innovation with generic drug competition.

13. Under the federal Food, Drug, and Cosmetic Act (FDCA),[1] manufacturers that create a new drug must obtain approval from the Food and Drug Administration (FDA) to sell the product by filing a New Drug Application (NDA).[2] An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.[3]

14. When the FDA approves a brand manufacturer's NDA, the manufacturer may list in *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the "Orange Book") certain kinds of patents that the manufacturer asserts could reasonably be enforced against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the

[1] Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended in 21 U.S.C. § 301 *et seq.*).

[2] 21 U.S.C. §§ 301-392.

[3] 21 U.S.C. § 355(a), (b).

expiration of the listed patents.[4] The manufacturer may list in the Orange Book within 30 days of issuance any patents issued after the FDA approved the NDA.[5] Valid and infringed patents may lawfully prevent generic competition, at least for a period, but manufacturers can abuse the system to use invalid or non-infringed patents to unlawfully delay generic competition.

15. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability because it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

1. Congress designed the Hatch-Waxman Amendments to the FDCA to encourage and hasten generic entry and reduce healthcare costs.

16. The FDCA's Hatch-Waxman Amendments, enacted in 1984, simplified regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs.[6] A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application (ANDA). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA and must show that the generic contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug and that it is bioequivalent, *i.e.*, absorbed at the same rate and to the same extent as the brand.

17. Drug products that the FDA considers therapeutically equivalent to the reference drug product are assigned an "A" code. This includes products for which "there are no known

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[4] For example, patents covering processes for making drug products may not be listed in the Orange Book.

[5] 21 U.S.C. § 355(b)(1), (c)(2).

[6] *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355).

or suspected bioequivalence problems" (AA, AN, AO, AP, or AT, depending on how the drug is administered) and drug products for which "actual or potential bioequivalence problems have been resolved with adequate *in vivo* and/or *in vitro* evidence supporting bioequivalence" (AB).[7]

18. The FDCA and Hatch-Waxman Amendments operate on the principle that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity, and identity are therapeutically equivalent and may be substituted for one another.

19. Through the Hatch-Waxman Amendments, Congress sought to expedite the entry of less expensive generic competitors to brand drugs, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

20. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches and ushering in an era of historically high profit margins for brand pharmaceutical manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, revenues for brand and generic prescription drugs totaled $21.6 billion; by 2013, total prescription drug revenues had climbed to more than $329.2 billion, with generics accounting for 86% of prescriptions.[8] Generics are dispensed about 95% of the time when a generic form is available.[9]

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[7] FDA, *Orange Book Preface*, available at https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface (last accessed June 20, 2025).

[8] *See* IMS Institute for Healthcare Informatics, *Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the United States in 2013* 30, 51 (2014).

[9] *Id.* at 51.

2. The FDA may grant regulatory exclusivities for new drugs, but those exclusivities do not necessarily bar generic entry.

21. To promote a balance between new drug innovation and generic drug competition, the Hatch-Waxman Amendments also provide for exclusivities (or exclusive marketing rights) for new drugs. The FDA grants any such exclusivities upon approval of a drug if the sponsor and/or drug meet the relevant statutory requirements. Any such exclusivities for a drug are listed in the Orange Book, along with any applicable patents, and can run concurrently with the listed patents.

22. One such exclusivity, the New Chemical Entity (NCE) exclusivity, applies to products containing chemical entities never previously approved by the FDA either alone or in combination. If a product receives NCE exclusivity, the FDA may not accept for review any ANDA for a drug containing the same active moiety for five years from the date of the NDA's approval.[10] If the patent holder filed a patent infringement suit filed within the one-year period beginning four years after NDA approval, the 30-month stay is extended by amount of time such that a total of 7.5 years will elapse from the date of NDA approval.

23. A drug product may also receive a three-year period of exclusivity if its sponsor submits a supplemental application (sNDA) that contains reports of new clinical investigations (other than bioavailability studies) conducted or sponsored by the sponsor that were essential to approval of the supplemental application. If this exclusivity is granted, the FDA may not approve an ANDA for that drug for three years from the date on which the supplemental application is approved.[11]

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[10] Unless the ANDA contains a certification of patent invalidity or non-infringement in which case an application may be submitted after four years. 21 U.S.C. § 355(j)(5)(F)(ii); 21 C.F.R. § 314.108(b)(2).

[11] 21 U.S.C. § 355(j)(5)(F)(iv); 21 C.F.R. § 314.108(b)(2)(5).

24. Regulatory exclusivities may not be absolute bars to generic entry. For example, some can be overcome by carving out information in the label or for other reasons.[12]

3. Abbreviated New Drug Applications must be accompanied by a certification under paragraphs I, II, III, and/or IV, the last of which can trigger an automatic stay.

25. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

a. That no patent for the brand has been filed with the FDA (a paragraph I certification);

b. That any patent(s) for the brand has/have expired (a paragraph II certification);

c. That any patent(s) for the brand will expire on a particular date and the manufacturer does not seek to market its generic before that date (a paragraph III certification); or

d. That any patent(s) for the brand is/are invalid or will not be infringed by the generic manufacturer's proposed product (a paragraph IV certification).[13]

26. If a generic manufacturer files a paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the paragraph IV certification, the FDA will not grant final approval to the ANDA-filer (which would enable the manufacturer to market and sell its product) until the earlier of (i) the passage of two-and-a-half years, or (ii) the issuance of a decision by a court that the patent at issue is invalid or not infringed by the generic

[12] *See, e.g.*, 21 C.F.R. §§ 314.94(a)(8)(iv), 314.127(a)(7); 21 U.S.C. § 355a(o).

[13] 21 U.S.C. § 355(j)(2)(A)(vii).

manufacturer's ANDA.[14] Until one of those conditions occurs, the FDA may only grant tentative approval, meaning the ANDA meets all regulatory requirements and is approvable but for the 30-month stay. FDA final approval may be delayed beyond the 30-month stay if the brand drug was entitled to the NCE exclusivity period.

27. Once the thirty-month stay ends (and the NCE exclusivity expires, if applicable) the FDA may grant an ANDA that meets all regulatory requirements final approval. Once the ANDA has received final approval, the generic manufacturer may launch its product, even if the patent litigation is still pending. This is known as an "at-risk" generic launch, the "risk" being that the generic manufacturer will have to pay the brand manufacturer its lost profits if the generic manufacturer launches its generic and later loses the patent litigation. However, where the generic manufacturer expects to ultimately prevail in the patent litigation, it is highly incentivized to launch at-risk. In one study of the 42 generic drugs that had received FDA approval and were not prevented by an injunction from launching, nearly two-thirds launched at risk.[15]

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[14] 21 U.S.C. § 355(j)(5)(B)(iii). This period is commonly called a 30-month Hatch-Waxman stay or 30-month stay. The brand/patent holder can choose to sue the generic after 45 days, including waiting until the generic has launched its product, but, in that event, the brand cannot take advantage of the 30-month stay of FDA approval, and must instead satisfy the showing required to obtain a preliminary injunction to prevent the generic launch.

[15] Keith M. Drake, Robert He, Thomas McGuire & Alice K. Ndikumana, *No Free Launch: At-Risk Entry By Generic Drug Firms,* National Bureau of Economic Research, Working Paper 29131, p. 18 (August 2021) ("Of the 42 generic drugs that had received FDA approval before a district court decision and were not prevented from entering by an injunction, 26 were launched at risk before a district court decision and 16 were not.") available at https://www.nber.org/papers/w29131.

4. The first ANDA filer to issue a paragraph IV certification is entitled, once approved, to 180 days as the only ANDA generic on the market.

28. To encourage manufacturers to seek approval of generic versions of brand drugs, the Hatch-Waxman Amendments grant the first paragraph IV generic manufacturer ANDA filer (first-filer) a 180-day exclusivity period to market the generic version of the drug. During that time, the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand drug.[16] That is, when a first-filer files a substantially complete ANDA certifying that the unexpired Orange Book patents covering the brand are invalid or not infringed, FDA cannot approve a later generic manufacturer's ANDA until the first-filer has been on the market for 180 days. The first filer's exclusivity period does not begin running until it, or another first filer, begins marketing its ANDA product.

29. A first filer who informs the FDA it intends to wait until all Orange Book-listed patents expire before marketing its generic, does not get a 180-day exclusivity period. Congress created this 180-day period to incentivize generic manufacturers to challenge weak or invalid patents or to invent around such patents by creating non-infringing generics.

30. The 180-day window is often referred to as the first filer's six-month or 180-day exclusivity; this is a bit of a misnomer, though, because a brand manufacturer can launch an authorized generic (AG) at any time, manufacturing its AG in accordance with its approved NDA for the branded product but selling at a lower price point. Also, the 180-day exclusivity period can be lost. One way a first filer may forfeit its 180-day exclusivity is by failing to obtain tentative approval from the FDA for its ANDA within 30 months of the ANDA filing. But failure to obtain tentative approval within the specified time period does not always result in

[16] 21 U.S.C. § 355(j)(5)(B)(iv), (D).

forfeiture. For example, if a change in the requirements for approval occurs, then the FDA may determine that the first filer has not forfeited its exclusivity. The FDA will commonly defer a decision on forfeiture until it becomes necessary to decide the issue, typically when a later filer seeks final approval for its ANDA product. At that time, FDA must decide whether the first filer has forfeited (clearing the way for final approval of the subsequent filer's ANDA) or whether the first filer has not forfeited (in which case final approval for the subsequent ANDA filer will be postponed until expiration of the first filer's 180-day exclusivity period).

5. Patents are subject to judicial and administrative scrutiny.

31. The existence of one or more patents purporting to cover a drug product does not guarantee a monopoly. Patents are routinely invalidated or held unenforceable, either upon reexamination or in *inter partes* proceedings by the U.S. Patent and Trademark Office (PTO), by court decision, or by jury verdict. A patent holder always bears the burden of proving infringement.

32. One way that a generic can prevail in patent infringement litigation is to show that its product does not infringe the patent (and/or that the patent holder cannot meet its burden to prove infringement). Another is to show that the patent is invalid or unenforceable.

33. A patent is invalid or unenforceable when: (i) the disclosed invention is anticipated and/or obvious in light of earlier prior art; (ii) its claims are indefinite, lack sufficient written description, or fail to properly enable the claimed invention; (iii) an inventor, an inventor's attorney, or another person involved with the application, with intent to mislead or deceive the PTO, fails to disclose material information known to that person to be material, or submits materially false information to the PTO during prosecution; and/or (iv) when a later acquired patent is not patentably distinct from the invention claimed in an earlier patent (and no exception, such as the safe harbor, applies) (referred to as "double patenting").

34. An assessment of whether a patent is obvious and therefore invalid is based on the prior art that existed as of the priority date of the claimed invention. "Prior art" refers to patents, published patent applications, and other non-patent sources, such as journal articles, that are publicly available. The "priority date" may be the date of the application for the claimed invention, or it may be an earlier date if the current patent application is a continuation of an earlier one. Further, "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."[17]

35. If the PTO rejects a patent application as obvious, a patent applicant may seek to overcome that rejection by submitting evidence that the claimed invention shows unexpected results, that is, that the claimed invention is at odds with what one would expect based on existing science.[18] "Consideration of rebuttal evidence and arguments requires Office personnel to weigh the proffered evidence and arguments."[19]

36. The patent examination process is *ex parte*, meaning that the patent examiner engages in a dialogue with the applicant. The public, third parties, and even researchers in the same field are not a part of the patent examination process. As a result, the patent process is not an adversarial proceeding, and it lacks the safeguard adverse parties pushing to present more facts to the examiner.

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[17] Manual of Patent Examining Procedure "MPEP" (8th ed. Rev. 7, July 2008) at § 2144.05.

[18] MPEP (8th ed. Rev. 7, July 2008) at § 2145 ("Rebuttal evidence may also include evidence that the claimed invention yields unexpectedly improved properties or properties not present in the prior art. Rebuttal evidence may consist of a showing that the claimed compound possesses unexpected properties. (internal citation omitted). A showing of unexpected results must be based on evidence, not argument or speculation.").

[19] *Id.*

37. Although patent examiners typically have a technical background, they face several challenges, including time limitations. In a recent study of approximately 50 participants, examiners reported that "they prioritize examination output (i.e., the number of patent applications reviewed) over the quality of the review. The examiners said that the USPTO focuses more on the volume of work completed, which can affect the thoroughness of examinations. . . . Examiners cited a variety of challenges in patent examination, including time pressures, and noted that patent applications have become more complex."[20] Further, "Examiners in all six focus groups said they aim to produce work that meets quality standards in the time they are given; however, in most of our focus groups, examiners noted they often do not complete a thorough search of prior art due to time constraints."[21] The report concluded that the "Patent Office should strengthen its efforts to address persistent examination and quality challenges."[22]

38. The PTO's decision to issue a patent does not substitute for a fact-specific assessment of (i) whether the applicant made intentional misrepresentations or omissions on which the PTO relied in issuing the patent, and (ii) whether a reasonable manufacturer in the patent holder's position would have a realistic likelihood of succeeding on the merits of a patent infringement suit.

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[20] *See* U.S. GOV'T ACCOUNTABILITY OFF., GAO-25-107218, INTELLECTUAL PROPERTY: PATENT OFFICE SHOULD STRENGTHEN ITS EFFORTS TO ADDRESS PERSISTENT EXAMINATION AND QUALITY CHALLENGES, at "GAO Highlights" (2025).

[21] *Id.* at 13.

[22] *Id.* at "GAO Highlights."

39. Unlike *ex parte* patent prosecutions, patent infringement litigations are adversarial proceedings in which sophisticated ANDA filers defend against infringement claims and affirmatively challenge the validity of the patent holder's patent claims.

40. As a statistical matter, if the parties litigate a pharmaceutical patent infringement suit to a decision on the merits, it is more likely that a challenged patent will be found invalid or not infringed than upheld. The FTC reports that generics prevailed in 73% of Hatch-Waxman patent litigation cases resolved on the merits between 1992 and 2002.[23] An empirical study of all substantive decisions rendered in every patent case filed in 2008 and 2009 similarly reports that when a generic challenger stays the course until a decision on the merits, the generic wins 74% of the time.[24]

41. If a generic manufacturer successfully defends against the brand's infringement lawsuit—either by showing that its ANDA does not infringe any asserted patents and/or that any asserted patents are invalid or unenforceable—the generic may enter the market immediately upon receiving approval from the FDA. Generic manufacturers are therefore incentivized to strongly defend against claims that they have infringed a valid patent.

42. There is a predictable pattern to the way brand drug companies develop their patent portfolios for blockbuster drugs. The first group of patents in the brand drug company's portfolio for the drug may reflect a genuine technological breakthrough that may later contribute to the success of the drug; these initial patents usually cover the active compound in a

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[23] FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* vi-vii (2002), available at https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf (last accessed June 20, 2025).

[24] John R. Allison, Mark A. Lemley & David L. Schwartz, *Understanding the Realities of Modern Patent Litigation*, 92 TEX. L. REV. 1769, 1787 (2014) ("[P]atentees won only 164 of the 636 definitive merits rulings, or 26%," and "that number is essentially unchanged" from a decade ago).

prescription drug or a particular pharmaceutical composition and may be correspondingly robust.

43. After filing applications for the original patents, the company continues its research and development efforts in the hopes of developing a drug product that could, eventually, be approved by the FDA. As the company's research matures, the patent filings continue, often for narrow modifications relating to specific formulations, methods of using the drug, or processes for creating the drug product disclosed in the original patent filings. But the original patent filings are now "prior art" and thus limit the scope of follow-on patents that can be obtained. New patents can be obtained for features of the drug only if the brand drug company can show that the new features are non-obvious distinctions over the growing body of prior art, which includes patents and printed publications, among other things. And often methods of using earlier inventions are disclosed by earlier compound or composition patents. Over time, as the number of patent filings for the drug grows, so does the volume of prior art beyond which the brand drug company must show non-obvious distinctions.

44. Patents present, at minimum, obstacles for would-be generic competitors to design around. Some patents broadly cover a drug's active ingredient and – if valid and enforceable – may prove impossible to design around while meeting the FDA's criteria for equivalent generics. While generic versions of the brand product may be able to obtain FDA approval and enter the market before all patents expire, once all the valid patents covering its blockbuster drug have expired, the brand drug company has no lawful means of preventing competitors from entering the market.

45. Therefore, a typical patent portfolio for a brand drug has its most significant patents issuing first; over time, the later- issued patents generally become increasingly narrow and more difficult to obtain. Even if the narrower coverage is obtained, these later-issuing

patents are more vulnerable to attack as invalid for covering subject matter that is old or obvious, and the narrower coverage is more easily designed around by would-be generics, thus preventing the brand from satisfying its burden of proving patent infringement to keep generics out of the market.

6. Patent applicants owe duties of candor and good faith to the PTO.

46. Because patent prosecution proceedings are *ex parte*, the PTO must receive all information from the applicant, and the applicant has a duty of candor and good faith in dealing with the PTO. As stated in the Manual of Patent Examining Procedure (MPEP), "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section."[25] Deceiving the PTO, engaging in inequitable conduct, including misleading the examiner or giving inaccurate statements during the prosecution, or violating the duty of disclosure renders the patent invalid.

47. For all documents submitted to the PTO, the applicant, "whether a practitioner or non-practitioner," must certify that all statements from "the party's own knowledge" or "on information and belief" are true.[26] Additionally, the applicant must acknowledge that any statements made that "knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or knowingly and willfully makes any false, fictitious, or

[25] 37 C.F.R. § 1.56(a) (2025).

[26] 37 C.F.R. § 11.18(b) (2025).

fraudulent statements or representations" will subject the applicant to penalties, including criminal penalties and "jeopardiz[ing] the probative value" of the filing.[27]

48. The "duty of candor and good faith [] is broader than the duty to disclose material information" and "'no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct.'."[28]

49. Expert opinion testimony "is entitled to consideration and some weight so long as the opinion is not on the ultimate legal conclusion at issue."[29] "In assessing the probative value of an expert opinion, the examiner must consider the nature of the matter sought to be established, the strength of any opposing evidence, the interest of the expert in the outcome of the case, and the presence or absence of factual support for the expert's opinion."[30] "[E]xpert opinion on what the prior art taught, supported by the documentary evidence and formulated prior to the making of the claimed invention, receive[s] considerable deference."[31]

7. Patent applicants owe a duty of disclosure to the PTO.

50. The duty to disclose information material to patentability applies to "[i]ndividuals associated with the filing or prosecution of a patent application" including "(1) Each inventor named in the application; (2) Each attorney or agent who prepares or prosecutes the application; and (3) Every other person who is substantively involved in the preparation or prosecution of

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[27] 37 C.F.R. § 11.18(b) (2025).

[28] MPEP (8th ed. Rev. 7, July 2008) at § 2001.04.

[29] MPEP (8th ed. Rev. 7, July 2008) at § 716.01(c).

[30] MPEP (8th ed. Rev. 7, July 2008) at § 716.01(c) citing *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.,* 776 F.2d 281, 227 USPQ 657 (Fed. Cir. 1985), *cert. denied,* 475 U.S. 1017 (1986).

[31] MPEP (8th ed. Rev. 7, July 2008) at § 716.01(c) citing *In re Carroll,* 601 F.2d 1184, 202 USPQ 571 (CCPA 1979).

the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application."[32]

51. Information cited in the information disclosure statement (IDS) (or otherwise submitted to the PTO) should not be incorrectly or incompletely characterized.[33]

52. "Materiality is not limited to prior art but embraces *any* information that a reasonable examiner would be substantially likely to consider important in deciding whether to allow an application to issue as a patent."[34]

53. "'A withheld reference may be highly material when it discloses a more complete combination of relevant features, even if those features are before the patent examiner in other references."[35]

54. To "help avoid problems with the duty of disclosure," the PTO recommends that applicants "avoid the submission of long lists of documents . . . . Eliminate clearly irrelevant and marginally pertinent cumulative information. If a long list is submitted, highlight those documents which have been specifically brought to applicant's attention and/or are known to be of most significance."[36]

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[32] MPEP (8th ed. Rev. 7, July 2008) at § 2001.01.

[33] MPEP (8th ed. Rev. 7, July 2008) at § 2004 ¶ 7 ("Care should be taken to see that prior art or other information cited in a specification or in an information disclosure statement is properly described and that the information is not incorrectly or incompletely characterized."); *see also id.* ("The duty of candor does not require that the applicant translate every foreign reference, but only that the applicant refrain from submitting partial translations and concise explanations that it knows will misdirect the examiner's attention from the reference's relevant teaching." quoting *Semiconductor Energy Laboratory Co. v. Samsung Electronics Co.*, 204 F.3d 1368, 1378 (Fed. Cir. 2000)).

[34] MPEP (8th ed. Rev. 7, July 2008) at § 2001.04 (quoting *Bristol-Myers Squibb Co. v. Rhode-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1234 (Fed. Circ. 2003)).

[35] MPEP (8th ed. Rev. 7, July 2008) at § 2004 ¶ 6 (quoting *Semiconductor Energy Laboratory Co. v. Samsung Electronics Co.*, 204 F.3d 1368, 1374 (Fed. Cir. 2000)).

[36] MPEP (8th ed. Rev. 7, July 2008) at § 2004 ¶ 13.

55. Where a false statement is made to the PTO, "[i]t does not suffice that one knowing of misrepresentations in an application or in its prosecution merely supplies the examiner with accurate facts without calling his attention to the untrue or misleading assertions sought to be overcome, leaving him to formulate his own conclusions."[37] Rather, the patent applicant must (i) "expressly advise the PTO of [the misrepresentation's] existence, stating specifically wherein it resides"; (ii) ensure that the PTO is "advised what the actual facts are, the applicant making it clear that further examination in light thereof may be required if any PTO action has been based on the misrepresentation"; and (iii) "on the basis of the new and factually accurate record, the applicant must establish patentability of the claimed subject matter."[38]

8. Foundational to patent law, the patent applicant must believe it is the "original and first" inventor of the claimed invention.

56. To obtain a patent, the claimed invention must be novel and nonobvious.[39] "The applicant shall make oath that he believes himself to be the original and first inventor of the process, machine, manufacture, or composition of matter, or improvement thereof, for which he solicits a patent."[40] The oath must "[s]tate that the person making the oath or declaration believes the named inventor or inventors to be the original and first inventor or inventors of the subject matter which is claimed and for which a patent is sought"[41] and "[s]tate that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in §1.56."[42]

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[37] *Rohm & Haas Co. v. Crystal Chemical Co.*, 722 F.2d 1556, 1572 (Fed. Cir. 1983).

[38] *Id.*

[39] 35 U.S.C. §§ 102, 103.

[40] 35 U.S.C. § 115 (1998) (current version at 35 U.S.C. § 115).

[41] 37 C.F.R. § 1.63(a)(4) (2012) (current version at 37 C.F.R. § 1.63).

[42] 37 C.F.R. § 1.63(b)(3) (2012) (current version at 37 C.F.R. § 1.63).

B. AB-rated generics quickly and dramatically drive down prices for purchasers.

57. Generic versions of brand drugs contain the same active ingredient(s) as the brand name drug and are determined by the FDA to be just as safe and effective as their brand counterparts. Because the brand and its A-rated generics are essentially commodities that cannot be therapeutically differentiated, the primary basis for competition between a brand product and its generic version, or between multiple generic versions, is price.

58. Without A-rated generics in the market, the manufacturer of a brand drug has a monopoly—every sale of the product, and the accompanying profit, benefits the brand manufacturer. Without A-rated generic competition, brand manufacturers can, and routinely do, sell their drug for far more than the marginal cost of production, generating profit margins above 70% while making hundreds of millions of dollars in sales. The ability to command these kinds of profit margins is what economists call market power.

59. When generic entry occurs, the brand manufacturer loses most of the unit sales; the generic manufacturer sells most of the units, but at reduced prices (which continue to decline). When multiple generics compete in the market, that competition drives prices down to near the marginal cost of production. This competition ends the brand manufacturer's market power and delivers enormous savings to drug purchasers. Competition converts what formerly were excess profits into purchaser savings.

60. According to a recent FDA study,[43] "[f]irst-generics often yield substantial cost savings. Generic drugs approved in 2018 yield annual savings of $17.8 billion, with $4.0 billion

[43] Ryan Conrad PhD, et al., *Estimated Cost Savings from New Generic Drug Approvals in 2018, 2019, and 2020* (August 2022), available at https://www.fda.gov/media/161540/download#:~:text=Estimates%20of%20the%20total%2012,estimated%20%2410.7%20billion%20in%20savings (last accessed June 20, 2025).

from first-generic approvals. Savings from 2019 approvals amount to $24.8 billion, with $9.4 billion coming from first-generic approvals. Savings from 2020 approvals are estimated at $10.7 billion, with first-generic approvals contributing $1.8 billion. Over all three years, first-generic approvals account for 29% of the total savings." The FDA also highlighted the price reductions associated with generic drug approvals, reporting that it "observe[d] many instances where, within a year of the first-generic approval, prices fall by more than 75% compared to the brand price."

1. The first AB-rated generic is priced below the brand, driving sales to the generic.

61. Experience and economic research show that the first generic manufacturer to market its product prices it below the prices of its brand counterpart.[44] Every state requires or permits that a prescription written for the brand be filled with an A-rated generic. Thus, the first generic manufacturer almost always captures a large share of sales from the brand. At the same time, there is a reduction in the average price paid for the drug at issue (brand and A-rated generic combined).

62. During the 180-day exclusivity period, the first filer is the only ANDA-approved generic manufacturer on the market. In the absence of competition from other generics, a first-filer generic manufacturer generally makes about 80% of all the profits that it will ever make on

[44] FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* ii-iii, vi, 34 (2011), available at https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf ("FTC 2011 AG Study") (last accessed June 20, 2025); FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, 4, (2010) available at https://www.ftc.gov/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study (last accessed June 20, 2025) at 1 ("FTC Pay-for-Delay Study").

the product during that 180-day exclusivity period, a significant incentive for getting to market as quickly as possible.

63. Once generic competition begins, it quickly captures sales of the corresponding brand drug, often 80% or more of the market within the first six months after entry. (This percentage erosion of brand sales holds regardless of the number of generic entrants.).

2. Later generics drive prices down further.

64. Once additional generic competitors enter the market, the competitive process accelerates, and multiple generic manufacturers typically compete vigorously with each other over price, driving prices down toward marginal manufacturing costs.[45] In one study, the Federal Trade Commission (FTC) found that on average, within a year of generic entry, generics had captured 90% of corresponding brand sales[46] and (with multiple generics on the market) prices had dropped 85%.[47]

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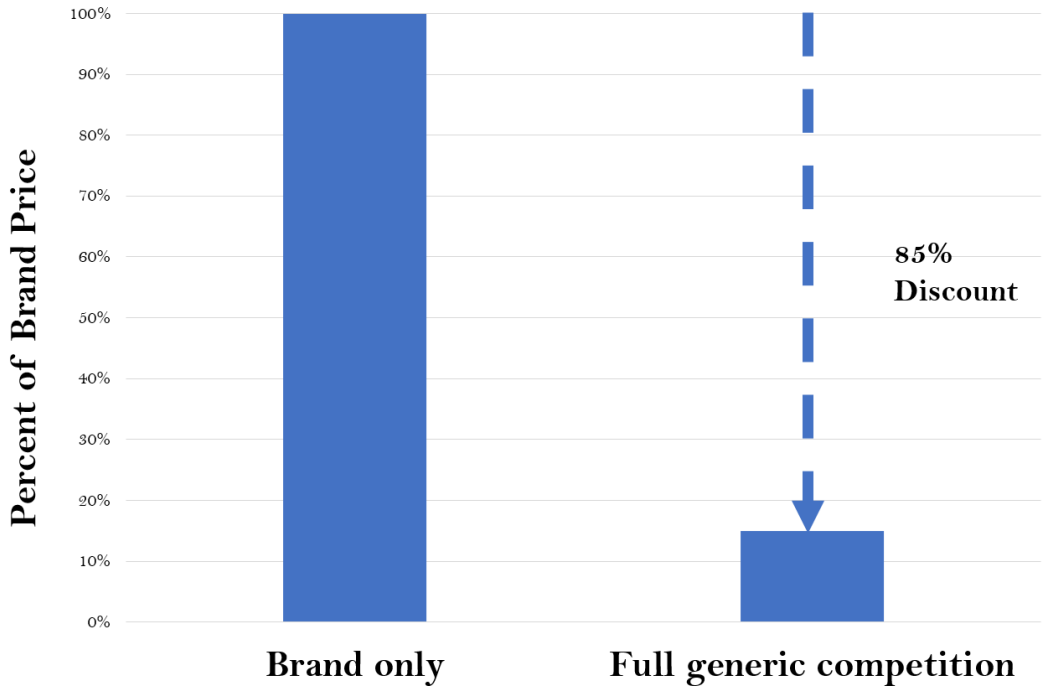
[45] *See, e.g.*, Tracy Regan, *Generic Entry, Price Competition, and Market Segmentation in the Prescription Drug Market*, 26 INT'L J. INDUS. ORG. 930 (2008); Richard G. Frank, The Ongoing Regulation of Generic Drugs, 357 NEW ENG. J. MED. 1993 (2007); Patricia M. Danzon & Li-Wei Chao, *Does Regulation Drive Out Competition in Pharmaceutical Markets?*, 43 J.L. & ECON. 311 (2000).

[46] For blockbuster drugs, such as Pomalyst, generic market share after one year is often higher than 90%.

[47] *See* FTC Pay-for-Delay Study.



65. According to the FDA and the FTC, the greatest price reductions occur when the number of generic competitors goes from one to two. The price of the drug drops between 50% to 80% from the brand price when there are multiple generic competitors on the market for a given brand. Consequently, the launch of a generic usually results in significant cost savings for all drug purchasers: "[a]lthough generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price."[48] According to the Congressional Budget Office, "generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics."[49]

[48] *See* "What Are Generic Drugs?," FDA (Aug. 24, 2017), available at https://www.fda.gov/drugs/generic-drugs/what-are-generic-drugs (last accessed Sept. 4, 2023).

[49] *Id.*

66. Generic competition enables all purchasers of a drug to (i) purchase generic versions of the drug at substantially lower prices, and/or (ii) purchase the brand at a reduced price. These competitive effects are known and reliable: brand sales decline to a small fraction of their level before generic entry and, as a result, brand manufacturers view competition from generics as a grave threat to their bottom lines.

67. Until a generic version of a brand drug enters the market, however, there is no FDA-approved bioequivalent drug to substitute for and compete with the brand, leaving the brand manufacturer to continue to profit by charging supra-competitive prices. Recognizing that generic competition will rapidly erode their brand sales, brand manufacturers seek to extend their monopoly for as long as possible, sometimes resorting to illegal means to delay or prevent generic competition.

3. Authorized generics, like other generics, compete on price.

68. An "authorized generic" (sometimes shortened to "AG") is a product sold under the authority of the brand's approved NDA. An AG is chemically identical to the brand drug but is sold as a generic, typically through either the brand manufacturer's subsidiary (if it has one) or through a third-party distributor.

69. If the 180-day exclusivity period applies to a first filer ANDA, the exclusivity exists only to bar the FDA from approving another ANDA during that time period. The exclusivity does not apply to products sold under the authority of the original NDA. As a result, the 180-day exclusivity does not bar the entry of authorized generics; the statutory scheme does not prevent a brand manufacturer from marketing and selling an AG at any time.

70. Brand manufacturers recognize the significant economic advantages of releasing their AGs to compete with the first-filer generic during the 180-day exclusivity period. One

study noted that "pharmaceutical developers facing competition from generics have large incentives to compete with their own or licensed 'authorized generics.'"[50]

71. Competition from an AG substantially reduces drug prices and the revenues of the first-filer generic (especially during the 180-day exclusivity period).

72. A study analyzing three examples of AGs found that "[f]or all three products, authorized generics competed aggressively against independent generics on price, and both the authorized and independent generics captured substantial market share from the brand."[51] The FTC similarly found that AGs capture a significant portion of sales, reducing the first-filer generic's revenues by about 50% on average. The first-filer generic makes much less money when it faces competition from an AG because (i) the AG takes a large share of unit sales away from the first filer; and (ii) the presence of the AG causes prices, particularly generic prices, to decrease.

73. Authorized generics are therefore a significant source of price competition. In fact, they are the only potential source of generic price competition during the first-to-file

[50] Kevin A. Hassett & Robert Shapiro, *The Impact of Authorized Generics on the Introduction of Other Generic Pharmaceuticals*, Sonecon LLC, 3 (May 2007) https://www.sonecon.com/wp-content/uploads/2022/01/050207_authorizedgenerics.pdf.

[51] Ernst R. Berndt, Richard Mortimer, Ashoke Bhattacharjya, Andrew Parece & Edward Tuttle, *Authorized Generic Drugs, Price Competition, and Consumer's Welfare*, 26 Health Affairs 790, 796 (2007).

generic manufacturer's 180-day exclusivity period. All drug industry participants recognize this. PhRMA recognizes it.[52] Generic companies recognize it.[53] Brand companies recognize it.[54]

V. FACTS

A. Background facts regarding the development of thalidomide and its analogs, including pomalidomide, for the treatment of cancers.

74. The following eleven sections of the complaint (sub-headings 1 through 11) allege facts regarding the state of known science regarding pomalidomide, its uses and its formulation, through the fall of 2002. In November of 2002, Celgene filed the first in a series of fraudulent patent applications to cover methods of use and formulations of pomalidomide. In summary, by November 2002 pomalidomide had been disclosed, including its use in the treatment of multiple myeloma, and its modest product formulation challenges well known. As the facts show, Celgene, along with co-conspirators Anthony Insogna (a principal attorney in the fraudulent patent prosecutions) and Jerome Zeldis (Celgene's medical director and the ostensible inventor for some of the fraudulently acquired patents) had personal and significant knowledge

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[52] Brand industry group PhRMA sponsored a study that concludes that the presence of an authorized generic causes generic prices to be more than 15% lower as compared to when there is no authorized generic. IMS Consulting, *Assessment of Authorized Generics in the U.S.* (2006).

[53] One generic stated that "[d]ue to market share and pricing erosion at the hands of the authorized [generic], we estimate that the profits for the 'pure' generic during the exclusivity period could be reduced by approximately 60% in a typical scenario." *See* FTC 2011 AG Study at 81. Another generic manufacturer quantified the fiscal consequences of competing with an authorized generic and determined that the authorized generic reduced its first generic's revenues by two-thirds, or by approximately $400 million. Comment of Apotex Corp. in Support of Mylan Citizen Petition at 4, Docket No. 2004P-0075 (Mar. 24, 2004), available at https://paragraphfour.com/uploads/educ/2004P0075Apotex.pdf.

[54] Commenting on an FDA petition by drug manufacturer Teva Pharmaceuticals, Pfizer stated: "Teva's petition [to prevent the launch of an authorized generic] is a flagrant effort to stifle price competition – to Teva's benefit and the public's detriment." Comment of Pfizer at 6-7, Docket No. 2004P-0261 (June 23, 2004); Comment of Johnson & Johnson at 1, FDA Docket No. 2004P-0075 (May 11, 2004).

regarding these public disclosures and prior art, and knew that there was no legally correct, reasonable basis upon which to seek patent protection for the pomalidomide uses and formulations.

1. Thalidomide and its analogs, including pomalidomide.

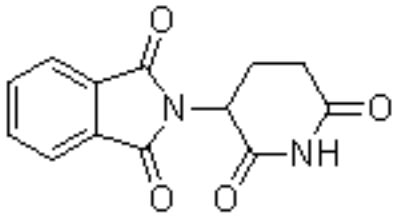
75. During the drug development process, once a promising compound is identified, scientists investigate both its properties and its analogs. An analog is a compound with similar chemical structure but differing in more than one respect.

76. Immunomodulatory drugs (IMiDs) are drugs that adjust immune responses. IMiDs also have anti-angiogenic effects, meaning they inhibit the ability of a tumor to grow its own blood vessels.

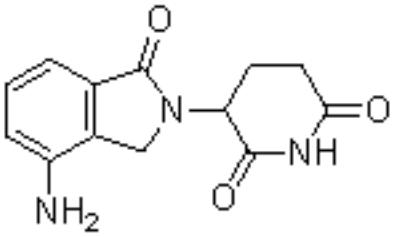
77. The IMiD class includes thalidomide and its analogs lenalidomide and pomalidomide.

78. This case involves wrongdoing regarding pomalidomide, the third of the thalidomide compounds to be marketed in the United States (the first being thalidomide, the second lenalidomide). Although pomalidomide was the third IMiD to be *marketed* in the United States, fundamental research for the use of thalidomide and its analogs, including pomalidomide and lenalidomide, to treat various conditions including multiple myeloma, occurred *concurrently*.

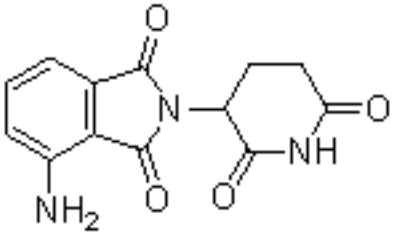
79. The chemical structure of thalidomide is:



80. The chemical structure of lenalidomide is:

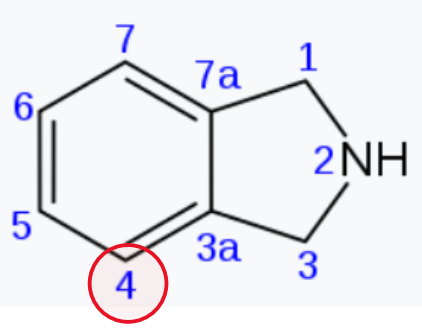


81. The chemical structure of pomalidomide is:



82. During research of a chemical compound, the drug is typically referred to by its chemical name. Because chemical names are often complex and cumbersome for general use, a shorthand version of the chemical name or a code name (such as CI 981) is developed for easy reference among researchers, and internally at a company there may be other code names. If the drug is eventually approved by the FDA, the compound is given an official generic name (such as atorvastatin) and, if applicable, a brand name (such as Lipitor). In the United States, the United States Adopted Names (USAN) Council assigns generic names.

83. The chemical name of pomalidomide is 4-(amino)-2-(2,6-dioxo(3-piperidyl))-isoindoline-1,3-dione. During research of the compound at issue in this case, the drug was at times referred to with the shortened chemical name "3-aminothalidomide" and at later times as "4-aminothalidomide". The leading number reflects the position on the isoindoline ring where the amino group ("NH2") connects. Whether the initial number for pomalidomide is considered "3" or "4" depends on where on the isoindoline ring the chemist begins counting. The numbering, subject to the naming conventions of the International Union of Pure and Applied Chemistry (IUPAC), changes based on which carbon the amino group is attached to. It's a uniform way for scientists to understand the compound of the structure.

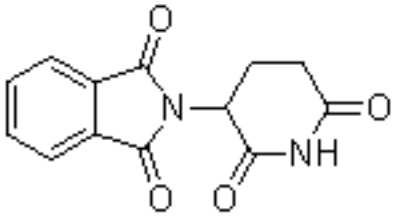
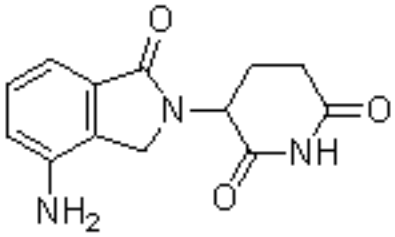
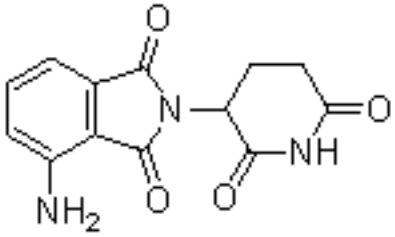
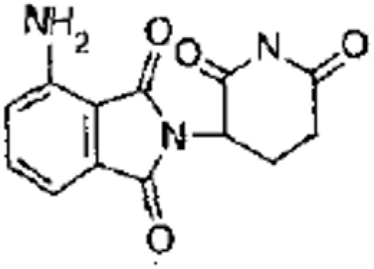


84. The point on the isoindoline ring above labeled as the "4 position" would instead be the "3 position" if the chemist began counting one position to the right (where the NH group attaches).

85. For pomalidomide, original studies described the amino group as attached to carbon 3 of the isoindoline ring and was referred to as "3-aminothalidomide." Later studies described the amino group as attached to carbon 4 of the isoindoline ring and referred to as "4-aminothalidomide." While careful review of diagrams can show whether it is, or is not, talking about the same molecule, different use of different terms can lead to confusion. (As later alleged, Celgene exploited the potential confusion regarding the compound name during patent prosecution).

86. Pomalidomide also had several other short-hand names, including ACTIMID and CC-4047. Eventually, the common generic name for the compound became "pomalidomide." For ease of understanding, these facts use the term "pomalidomide," except when quoting we of course use the exact reference used.

87. The table below summarizes the chemical names and other names used for thalidomide, lenalidomide, and pomalidomide.

Compound	Drawing	Chemical Name	Other Names
thalidomide (in Thalomid)		2-(2,6-dioxopiperidin-3-yl-1H-isoindole-1,3(2H)-dione	
lenalidomide (in Revlimid)		1-oxo-2-(2,6-dioxopiperidin-3-yl)-4-aminoisoindoline	Revimid; CC-5013
Pomalidomide (in Pomalyst)	 CAN ALSO BE DRAWN: 	1,3-dioxo-2-(2,6-dioxopiperidin-3-yl)-4-aminoisoindoline. 4-(amino)-2-(2,6-dioxo(3-piperidyl))-isoindoline-1,3-dione	3-aminothalidomide; 4-aminothalidomide; ACTIMID; CC-4047; CDC 394; S-3-Amino-phthalimido-glutarimide

2. 1960s to 1990s—the study of thalidomide and its analogs.

88. In 1957, thalidomide was originally approved for use in West Germany. Thalidomide gained international attention in the 1960s. It was often prescribed to pregnant women to treat morning sickness. But it became known that thalidomide, when taken during a critical phase of pregnancy, could cause particularly severe birth defects, primarily resulting in the malformation or absence of a limb of the affected children. Substances that interfere with

normal fetal development and/or cause congenital disabilities are referred to as "teratogens" or "teratogenic."

89. In 1961, the drug was banned after its teratogenic properties were observed. (Indeed, the thalidomide fiasco is often attributed as leading to major reforms in U.S. drug approval process).

90. Several years after thalidomide was withdrawn from the market for its ability to induce severe birth defects, its anti-inflammatory properties were discovered when patients with erythema nodosum leprosum (ENL), a condition associated with leprosy,[55] used thalidomide as a sedative, and it reduced both the clinical signs and symptoms of the disease.

91. The discovery of the anti-angiogenic and anti-inflammatory properties of thalidomide would lead to the development of analogs of thalidomide as a new way of fighting cancer as well as some inflammatory diseases. The notion was that analogs of thalidomide might be more effective and/or safer, and reduce thalidomide's teratogenic side effects, high incidence of other adverse reactions, poor solubility in water, and poor absorption from the intestines.

92. Pomalidomide was one of the analogs showing promising properties. As early as 1965, pomalidomide was known to be an analog of thalidomide that caused dysmelia: i.e.,

[55] *See* Teo S, Resztak KE, Scheffler MA, Kook KA, Zeldis JB, Stirling DI, Thomas SD., *Thalidomide in the treatment of leprosy.* Microbes Infect. 2002 Sep;4(11):1193-202. doi: 10.1016/s1286-4579(02)01645-3. PMID: 12361920. (stating that thalidomide has been used to treat ENL since the 1960s), available at https://pubmed.ncbi.nlm.nih.gov/12361920/sd (last accessed June 20, 2025).

malformation of limbs and extremities.[56] By the 1970s and early 1980s, pomalidomide was known to be an analog of thalidomide that could cause similar birth defects.[57]

93. In the early 1990s, multiple studies reported that thalidomide was discovered to inhibit tumor necrosis factor-alpha (TNFα).[58] In healthy people, TNF helps the immune system fight infections and kills tumor cells. It encourages modest inflammation, which helps the body heal. In patients with autoimmune conditions, TNF can cause excessive inflammation and worsen symptoms.

94. TNFα is a cytokine - a type of signaling molecule in the immune system - produced by various cells, such as macrophages, in response to infection, injury, or other inflammatory stimuli. TNFα plays a crucial role in inflammation and immune response. However, elevated levels of TNFα are associated with a few diseases, including cancer.[59]

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[56] *See* R.L. Smith, et al., *Studies on the Relationship Between the Chemical Structure and Embryotoxic Activity of Thalidomide and Related Compounds*, A Symposium on Embryopathic Activity of Drugs, London (1965).

[57] *See* H. Koch, *The Arene Oxide Hypothesis of Thalidomide Action - Considerations on the Molecular Mechanism of Action of the Classic Teratogen*, sci. phann., p. 49, 67—99 (1981); N.A. Jonsson, *Chemical Structure and teratogenic properties*, acta pharm. Succica, 9:521—542 (1972).

[58] Sampaio, Sarno, Galilly Cohn and Kaplan, JEM 173 (3) 699–703, 1991; Sampaio EP, Kaplan G, Miranda A, Nery J.A., Miguel CP, Viana SM, Sarno EN. *The influence of thalidomide on the clinical and immunologic manifestation of erythema nodosum leprosum*. J Infect Dis. 1993 Aug;168(2):408-14. doi: 10.1093/infdis/168.2.408. PMID: 8335978 ("Patients with systemic ENL demonstrated the highest serum TNF alpha levels, which decreased significantly during thalidomide treatment.").

[59] De SK, Devadas K, Notkins AL. Elevated levels of tumor necrosis factor alpha (TNF-alpha) in human immunodeficiency virus type 1-transgenic mice: prevention of death by antibody to TNF-alpha. J Virol. 2002;76(22):11710-11714. doi:10.1128/jvi.76.22.11710-11714.2002 ("Elevated levels of circulating TNF-α have been linked to a wide variety of diseases, including arthritis, diabetes, Crohn's disease, and cachexia associated with terminal cancer and AIDS."), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC136749/#:~:text=Elevated%20levels%20of%20circulating%20TNF,cancer%20and%20AIDS%20(23) (last accessed June 20, 2025).

Scientists posited that, if thalidomide-like compounds could reduce TNFα, they could potentially be used to treat cancer or autoimmune conditions.

95. The renewed interest in thalidomide to treat a host of diseases, including cancer, extended beyond the scientific community, and was reported widely in the media.[60] And so, by the early 1990s, multiple research groups across the country were studying the use of thalidomide and its analogs to treat cancers, AIDs, and other conditions.

3. 1990s: D'Amato and Boston Children's Hospital's investigations and patents.

96. In the 1990s, researchers at Children's Hospital in Boston were investigating whether they could slow tumor growth by cutting off or restricting blood flow to the area. They hypothesized that solid tumors require angiogenesis, or the development of blood vessels, for their growth and maintenance. At least as early as 1992, one of the researchers, Dr. Robert D'Amato, began a search for compositions that would inhibit undesired angiogenesis in humans and animals. After careful and laborious testing, D'Amato discovered that thalidomide inhibits angiogenesis or is "anti-angiogenic". That is, thalidomide interferes with the development and maintenance of blood vessels.

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[60] *See e.g.,* Lawrence Altman, *Researchers Testing Thalidomide for Use in AIDS,* N.Y. Times (July 1, 1993) ("Thalidomide works in laboratory experiments against H.I.V. by selectively suppressing a natural substance produced in the body, the authors reported in the Proceedings of the National Academy of Sciences. The substance, tumor necrosis factor, also called cachectin, defends against infection, and it has been the subject of intense research in cancer and many other diseases."), available at https://www.nytimes.com/1993/07/01/us/researchers-testing-thalidomide-for-use-in-aids.html (last accessed June 20, 2025).

See also Sandra Blakeslee, *Scorned Thalidomide Raises New Hopes,* N.Y. Times (Apr. 10, 1990), available at https://www.nytimes.com/1990/04/10/science/scorned-thalidomide-raises-new-hopes.html (last accessed June 20, 2025); *see also* Washington Post (Apr. 11, 1991), *Drug Firms Seek to Make Thalidomide for Research,* available at https://www.washingtonpost.com/archive/politics/1991/04/11/drug-firms-seek-to-make-thalidomide-for-research/bead3a71-7d37-4948-a917-eb8c0aa253b2/ (last accessed June 20, 2025).

97. Once D'Amato and others discovered thalidomide's anti-angiogenic properties, they began investigating whether it and its analogues could be used to treat conditions associated with angiogenesis, such as cancers, blood cancers, tumors, arthritis, and autoimmune conditions.

98. Over the next decade, D'Amato and other researchers at Children's Hospital extensively studied the properties and uses of thalidomide, lenalidomide, pomalidomide, and many other analogues. And they developed a large portfolio of intellectual property regarding those analogues.

99. For example, a series of patent applications (starting with a priority date of March 1, 1993) disclosed that thalidomide and other analogs, including lenalidomide and pomalidomide, were useful in treating numerous diseases mediated by angiogenesis, such as cancer, both blood-borne and solid tumors, chronic inflammation, such as rheumatoid arthritis and osteoarthritis, and other inflammatory diseases, such as ulcerative colitis and Crohn's disease. The patent applications disclosed suitable routes for administration of the active ingredients. The applications stated that, "angiogenesis inhibition is generally an important mechanism for the operation of teratogenic compounds (particularly compounds that cause dysmelia; i.e., malformation of limbs and extremities). Such anti-angiogenic compounds generally can be used to treat diseases characterized by undesired angiogenesis."

100. In 1994, Dr. D'Amato published an article explaining how thalidomide was found to have anti-angiogenic activity. D'Amato RJ, Loughnan MS, Flynn E, Folkman J (April 1994), *Thalidomide is an inhibitor of angiogenesis,* Proc. Natl. Acad. Sci. U.S.A. 91 (9): 4082. ("D'Amato 1994").

101. In addition to testing thalidomide's effect on angiogenesis, D'Amato tested other compounds, including pomalidomide, which he routinely referred to as "3-amino thalidomide". During the 1990s, D'Amato obtained several patents claiming or teaching the use of 3-amino

thalidomide (i.e., pomalidomide) as a method of treating undesired angiogenesis in a human or animal. Those patents include the 5,593,990 ('990), 5,629,327 ('327), and 5,712,291 ('291) ("the D'Amato patents").

102. D'Amato's research into thalidomide and its analogs and his growing patent portfolio would begin to threaten Celgene's investigations in the same area. D'Amato's research pre-dated that of Celgene, and presented a body of prior art that would undermine Celgene's attempts to patent the same thalidomide analogs.

4. 1990s: Celgene's investigations and the '517 patent.

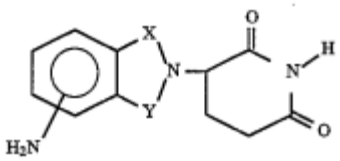
103. During the 1990s, Celgene researchers also explored the development of thalidomide and its analogs for their anti-angiogenic and anti-myeloma activities.

104. On July 24, 1996, Celgene[61] filed patent application no. 08/690,258, which led to the 5,635,517 (the "'517 patent"). The '517 patent identified analogs of thalidomide, including lenalidomide and pomalidomide, as compounds decreasing TNFα levels. As the '517 patent explains, "[d]ecreasing TNFα levels . . . constitutes a valuable therapeutic strategy for the treatment of many inflammatory, infectious, immunological or malignant diseases. . . . These include but are not limited to . . . cancer . . . ."

105. The '517 patent has two independent claims (Claim 1 and 10). Claim 1 claims:

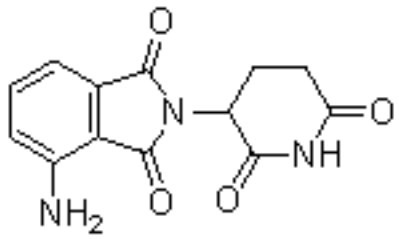
> "The method of reducing undesirable levels of TNFα in a mammal which comprises administering thereto an effective amount of a compound of the formula:

[61] The inventors on the patent are listed as George Muller, David Stirling, and Roger S.C. Chen., all of whom worked for Celgene. The assignee of the patent is Celgene Corporation. Because the inventors were affiliated with Celgene, and Celgene was the assignee of the patent when issued, we refer to the patent applicant as simply "Celgene." For simplicity and clarity, we have adopted this convention when referring to the relevant patent prosecutions.



in which said compound one of X and Y is C=O and the other of X and Y is C=O or CH."

106. One variation encompassed by Claim 1 is a method of reducing TNFα with a compound with the structure depicted above, where X and Y both have a carbon atom double bonded to an oxygen atom (represented above as "C=O"). As shown below, this is pomalidomide:



107. Claim 7, a dependent claim, claims this specific variation in the formula, that is, "The method according to claim 1 in which each of X and Y is C=O."

108. Claim 8, also a dependent claim, claims "The method according to claim 7 in which said compound is 1,3-dioxo-2-(2,6-dioxopiperidin-3-yl)-4-aminoisoindoline." This is simply the chemical name for pomalidomide.

109. Putting all of that together, Claims 1, 7, and 8 of the '517 claim methods of using pomalidomide to reduce TNFα. (The '517 patent does not claim the compound pomalidomide by itself; the claim in the '517 patent that claims a compound by itself is Claim 10 which does claim four compounds, but none are pomalidomide).

110. Thus, as early as 1996, Celgene owned a patent that claimed a method of using pomalidomide to reduce TNFα, which the '517 discloses is "a valuable therapeutic strategy for the treatment of. . . . cancer. . . ."[62]

111. The '517 patent also claims the compound lenalidomide (i.e., brand Revlimid) and methods of using lenalidomide to reduce undesirable levels of TNFα. The '517 patent would later become the foundation of Celgene's Revlimid franchise, earning it $35,610 million in revenue in the U.S. in the last five years alone. Revlimid, in combination with the steroid dexamethasone, is used primarily in the treatment of multiple myeloma, a blood cancer.

5. 1990s: Celgene hired Dr. Jerome B. Zeldis and Anthony Insogna.

112. In or about 1996, Celgene first retained Anthony Insogna. At the time, Insogna was a patent attorney at the New York law firm of Pennie & Edmonds. Insogna would work at Pennie & Edmonds on behalf of Celgene for years, with an emphasis on intellectual property protection for ostensible inventions relating to thalidomide and its analogs. In 2003, Insogna became employed by the law firm Jones Day, and continued his work for Celgene.

113. Also, in the 1990s Celgene hired Dr. Jerome B. Zeldis. Zeldis joined Celgene in 1997 as Vice President of Medical Affairs. Zeldis has a scientific background and holds an MD and a PhD in Molecular Biophysics and Biochemistry. In 1999, Zeldis was named Chief Medical Officer at Celgene, where he was responsible for identifying new disease targets for Celgene's drugs and crafting studies and clinical trials to support Celgene's New Drug Applications.

114. As shown below, both Insogna and Zeldis, through their work with Celgene, had personal and significant knowledge regarding public disclosures and prior art, predating late 2002, regarding pomalidomide and its uses and formulation.

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[62] *See* the '517, column 3, lines 59─67.

6. 1998-2002: Reissuance proceedings for the '517 patent show knowledge of pomalidomide and its properties.

115. In early 1998, Celgene realized that the '517 patent, the cornerstone of its thalidomide analog patents, might be invalid due to earlier patents granted to D'Amato and other Children's Hospital researchers.

116. On April 14, 1998, Celgene sought reexamination of the '517 to clear it from the specter of the potentially invalidating D'Amato patents.

117. In December 1998, Celgene entered into a license agreement with Children's Hospital (and its development partner, EntreMed) under which Celgene bought some license rights to the early D'Amato patents.

118. Celgene's effort to clear the '517 backfired. On February 21, 1999, the PTO rejected all claims of the '517 as unpatentable over the three D'Amato patents (the 5,593,990, 5,629,327, and 5,712,291) and in view of the two other references.[63] In explaining its determination that the claims were unpatentable as obvious, the PTO stated: "the record has shown and the patentee has admitted in the record that the 3 D'Amato patents contain the same disclosure and said D'Amato patents, *supra*, disclose the very closely analogous compounds, . . .and methods for their preparation." The examiner further stated that the record showed that "[the] concept of angiogenesis and administering said reference compounds to a patient with toxic concentrations of TNF-α is taught [in the D'Amato patents]." The examiner, therefore concluded, "[s]ince the properties of the prior art overlap with the ['517] under reexamination, and the 3-D'Amato patents teach the equivalents . . . there is ample information

[63] U.S. Patent No.4,808,402 (Leibovich is a named inventor) and Leibovich et al., *Macrophage-Induced Angiogenesis is Mediated Tumor Necrosis factor-a*, Letters To Nature, Vol.329, 630─32, (filed Oct. 15, 1987).

in the prior [art] to motivate one of ordinary skill in the chemical arts to place applicants [sic] compounds in possession of the public."[64]

119. In February 1999, to resurrect its '517 patent, Celgene filed for reconsideration and presented a declaration by its then-Chief Scientific Officer, David I. Stirling. The data described by Stirling purported to show that "Compound 2" (which in fact was pomalidomide) was 10,000-fold more active than another compound (4-hydroxythalidomide) in the primary human cell-based assay.

120. For purposes of this case, it is not directly relevant that Celgene's statements its reconsideration request were materially false in reviving the '517 patent. The statements both vastly exaggerated the extent to which "Compound 2" outperformed the other chemical, and misleadingly suggested "Compound 2" was lenalidomide (when in fact it was pomalidomide). Instead, the reexamination proceedings show that it was public knowledge that careful review of the '517 patent showed that it claimed methods of using pomalidomide, and that pomalidomide had been tested as a powerful thalidomide analog in inhibiting TNFα.

121. On March 9, 1999, the examiner issued a Statement of Reasons for Patentability and/or Confirmation that allowed the patent to re-issue because the examiner believed the "claimed compound" was shown to be superior:

> The data presented in the Dr. David I. Sterling [sic] Declaration, kindly furnished under the provisions of 37 C.F.R. 1.132 clearly shows unexpected superior results when the claimed compound, namely, 7-amino-1-oxo-2(2,6-dioxo-piperidin-3-yl)-isoindoline,[65]

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[64] Application No. 90/005,157.

[65] "7-amino-1-oxo-2(2,6-dioxo-piperidin-3-yl)-isoindoline" corresponds to the fourth compound claimed in Claim 10 of the '517, *i.e.* 1-oxo-2-(2,6-dioxopiperidin-3-yl)-7aminoisoindoline. The patent examiner most likely meant Compound 2 (which is pomalidomide in the Sterling Declaration) when he referenced 7-amino-1-oxo-2(2,6-dioxo-

> when compared to the corresponding 7-hydroxy -1-oxo-2(2,6-dioxo-pi_peridin-3-yl)-isoindoline of the prior art in a side-by-side comparison. . . . Looking at the data, the claimed compound is clearly superior in the inhibition of TNF-alpha (Tumor Necrosis Factor) at concentration levels IC_{50}. (emphasis added).

122. Although Celgene ultimately managed to convince the examiner to reissue the '517, Celgene was on notice and could no longer ignore that there was broad, public information about i) thalidomide analogs, ii) the relative activities of the analogs could vary widely, and iii) that effectiveness of pomalidomide had now been publicly disclosed by Celgene itself.

7. 1998: Celgene seeks a leprosy-related indication for thalidomide.

123. Meanwhile, Celgene had been pursuing FDA approval of thalidomide to treat erythema nodosum leprosum (ENL).

124. On July 15, 1998, the FDA approved Celgene's new drug application for thalidomide 50 mg for the acute treatment of the cutaneous manifestations of moderate to severe ENL. While the approved indication was for ENL, given increasing scientific research showing the ability of thalidomide (and its analogs) to inhibit TNFα and its effect on multiple myeloma, over time (before the 2006 formal approval for multiple myeloma) thalidomide was used off-label to treat multiple myeloma.

125. Multiple myeloma is a cancer that forms in plasma cells. Plasma cells are a type of white blood cell. In healthy individuals, plasma cells help fight infections by making antibodies. In multiple myeloma patients, cancerous plasma cells build up in the bone marrow and crowd out the healthy blood cells.

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piperidin-3-yl)-isoindoline. The Sterling Declaration makes no mention of 7 aminoinoisindoline. The declaration, however, states that compound 2 is clearly superior in the inhibition of TNF-alpha.

126. Following the approval of thalidomide for ENL, the scientific community continued to report on thalidomide analogs, such as pomalidomide, including regarding their effect on multiple myeloma, relative potency, and the ability of thalidomide analogs (such as lenalidomide and pomalidomide) to treat relapsed or refractory disease.

127. For example, on June 7, 1999, the journal of Bioorganic & Medicinal Chemistry Letters published a study by G.W. Muller and others ("Muller (1999)")[66] disclosing the structure of pomalidomide and teaching that "4-amino substituted analogs were found to be potent inhibitors of TNF-α." On July 1, 1999, the Journal of Immunology published a study by L.G. Corral and others ("Corral (1999)")[67] teaching pomalidomide[68] as a more potent agent with decreased potential for birth defects. In 2000, the journal Blood published a study by Hideshima and others ("Hideshima (2000)") regarding the ability of thalidomide and its analogs to overcome drug resistance of multiple myeloma cells.[69]

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[66] Muller GW, Chen R, Huang SY, Corral LG, Wong LM, Patterson RT, Chen Y, Kaplan G, Stirling DI. *Amino-substituted thalidomide analogs: potent inhibitors of TNF-alpha production*. Bioorg Med Chem Lett. 1999 Jun 7;9(11):1625-30. doi: 10.1016/s0960-894x(99)00250-4. PMID: 10386948, available at https://www.sciencedirect.com/science/article/abs/pii/S0960894X99002504?via%3Dihub (last accessed June 20, 2025).

[67] Corral LG, Haslett PA, Muller GW, Chen R, Wong LM, Ocampo CJ, Patterson RT, Stirling DI, Kaplan G. *Differential cytokine modulation and T cell activation by two distinct classes of thalidomide analogues that are potent inhibitors of TNF-alpha*. J Immunol. 1999 Jul 1;163(1):380-6. PMID: 10384139, available at https://pubmed.ncbi.nlm.nih.gov/10384139/ (last accessed June 20, 2025).

[68] Pomalidomide is referred to in the study as "compound CI-A."

[69] Teru Hideshima, Dharminder Chauhan, Yoshihito Shima, Noopur Raje, Faith E. Davies, Yu-Tzu Tai, Steven P. Treon, Boris Lin, Robert L. Schlossman, Paul Richardson, George Muller, David I. Stirling, Kenneth C. Anderson; *Thalidomide and its analogs overcome drug resistance of human multiple myeloma cells to conventional therapy*. Blood 2000; 96 (9): 2943–2950. doi: https://doi.org/10.1182/blood.V96.9.2943 (last accessed June 20, 2025).

8. 2000-2002: Celgene applies for and obtains the '230 and '554 patents, both disclosing pomalidomide can be used to reduce TNFα.

128. On April 6, 2000, Celgene filed a patent application (in the '517 family) that led to the 6,281,230 (issued in 2001). The '230 claims methods of treatment involving lenalidomide to treat cancerous conditions and reduce TNFα. It also disclosed pomalidomide in combination with an active agent as part of the '230 methods of treatment claims.

129. On February 12, 2001, Celgene filed a patent application (again in the '517 family) that led to the 6,555,554 (issued in 2003). The '554 claimed methods of treatment involving lenalidomide to improve oncogenic or cancerous conditions and reduce TNFα. As with the '230, the '554 also disclosed pomalidomide in its methods of treatment claims.

130. Like the '517, the '230, and the '554 both publicly disclosed that pomalidomide can be used to reduce TNFα.

9. 2000-2002: Scientists continue to publish about pomalidomide's features and benefits.

131. The scientific community continued to study and publish on the potency of thalidomide analogs and the use of thalidomide in combination with dexamethasone to treat multiple myeloma.

132. For example, Weber, et al., Abstract #719, *Thalidomide with dexamethasone for resistant multiple myeloma*, Blood, 96(11):167a (2000) ("Weber (2000)") disclosed the clinical efficacy of thalidomide with dexamethasone to treat resistant multiple myeloma.

133. On July 1, 2001, the American Society of Hematology journal Blood published a study by Davies and others ("Davies (2001)"),[70] which disclosed that thalidomide and immunomodulatory drugs (referred to in the study as IMiD1, IMiD2, and IMiD3) can act directly on multiple myeloma cells and are useful in relapsed/refractory disease. Davies (2001) further disclosed that the new thalidomide analogs are 50,000 times more potent in inhibiting TNFα as compared to thalidomide. As explained above, "IMiDs" was a term coined by Celgene, referring most prominently to pomalidomide and lenalidomide.

134. On December 1, 2001, Robert A. Kyle and others ("Kyle (2001)")[71] published an article disclosing a method of treating multiple myeloma by administering thalidomide in combination with dexamethasone cyclically.

135. Also in December 2001, Dimopoulos, et al., *Thalidomide and dexamethasone combination for refractory multiple myeloma*, Ann. Oncology, 12:991-995 (2001) ("Dimopoulos (2001)") disclosed *inter alia* thalidomide plus dexamethasone to treat refractory multiple myeloma.

136. The prior art also disclosed the specific amount of 40 mg of dexamethasone plus thalidomide for the treatment of multiple myeloma.[72]

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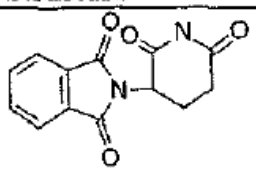
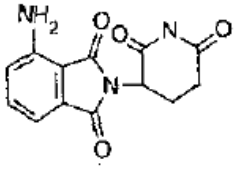
[70] Davies FE, Raje N, Hideshima T, Lentzsch S, Young G, Tai YT, Lin B, Podar K, Gupta D, Chauhan D, Treon SP, Richardson PG, Schlossman RL, Morgan GJ, Muller GW, Stirling DI, Anderson KC. *Thalidomide and immunomodulatory derivatives augment natural killer cell cytotoxicity in multiple myeloma*. Blood. 2001 Jul 1;98(1):210-6. doi: 10.1182/blood.v98.1.210. PMID: 11418482, available at https://pubmed.ncbi.nlm.nih.gov/11418482/ (last accessed Sept.4, 2023).

[71] Kyle, Robert A, and S. Vincent Rajkumar. *Therapeutic Application of Thalidomide in Multiple Myeloma*. Seminars in Oncology 28, no. 6 583–87 (Dec. 1, 2001) doi:10.1016/S0093- 7754(01)90028- 4, summary available at https://journals.scholarsportal.info/details/00937754/v28i0006/583_taotimm.xml (last accessed June 20, 2025).

[72] *See* Coleman, et al., *BLT-D (Clarithrmycin [Biaxin], Low-Dose Thalidomide, and Dexamethasone) for the Treatment of Myeloma and Waldenstroms Macroglobulinemia*, Leukemia & Lymphona, 43(9):1777─1782 (2002) ("Coleman (2002)").

137. These disclosures regarding the use of thalidomide in combination with 40 mg of dexamethasone to treat multiple myeloma were in addition to the much earlier disclosures regarding the cyclical dosing of an anticancer drug (hexamethylamine) for the treatment of multiple myeloma, *i.e.,* 21 consecutive days of administration of the anticancer drug followed by 7 days of rest, in combination with dexamethasone.[73]

138. The prior art also taught the specific thalidomide analog pomalidomide for the treatment of multiple myeloma. In December 2001, Robert J. D'Amato and others published an article entitled *Mechanisms of Action of Thalidomide and 3-Aminothalidomide in Multiple Myeloma* (the "D'Amato (2001)").[74] A diagram in the article (shown below) reveals that the compound discussed in the study is pomalidomide:

Compound	Structure	bFGF Inhibition	VEGF Inhibition
Thalidomide		39%	41%
3-Aminothalidomide		30%	42%

139. But one would not know this from the title of the article unless he or she was familiar with D'Amato's idiosyncratic use of the term "3-aminothalidomide" to refer to

[73] *See* Cohen, et al., *Hexamethylamine and prednisone in the treatment of refractory multiple myeloma*, Am. J. Clin. Oncol. (CCT), 5:21—27 (Feb. 1982) ("Cohen (1982)").

[74] Robert J D'Amato, Suzanne Lentzsch, Kenneth C Anderson, Michael S Rogers, *Mechanism of action of thalidomide and 3-aminothalidomide in multiple myeloma*, Seminars in Oncology, Volume 28, Issue 6, 2001, 597–601, ISSN 0093-7754, https://doi.org/10.1016/S0093-7754(01)90031-4 (last accessed June 20, 2025).

pomalidomide. A scientist would not have any reason to suspect that D'Amato meant pomalidomide (also known as "4-aminothalidomide") when he said "3-aminothalidomide," a that term suggests that the amino group attaches at the 3-position of the benzene ring, rather than the 4-position, as is the case with pomalidomide.

140. D'Amato (2001) taught pomalidomide for the treatment of multiple myeloma, stating that pomalidomide "exhibited an unusual capacity to directly inhibit myeloma proliferation." It noted that pomalidomide directly inhibited myeloma cell proliferation and thus inhibited multiple myeloma both on the tumor and vascular compartments. The dual activity of pomalidomide was reported to make it more efficacious than thalidomide. This effect was reported to be unrelated to TNFα inhibition since potent TNFα inhibitors such as rolipram and pentoxifylline did not inhibit myeloma cell growth nor angiogenesis.[75]

141. Also in December 2001, Lentzsch et al., Abstract #1976, *S-3-Amino-phthalimido-glutarimide Inhibits Growth in Drug Resistant Multiple Myeloma (MM) In Vivo,* Blood, 43rd Annual Amer. Soc. Hematol. (Dec. 7-11, 2001), 98(11): 473a (2001) ("Lentzsch (2001)") disclosed that pomalidomide (referred to in the article as S-3-Amino-phthalimido-glutarimide or S-3APG for short) has notable anti-multiple myeloma activity, concluding that "[o]ur results show that S-3APG could be a potent new drug for the treatment of MM. S-3APG exerts its anti-myeloma activity by combination of direct dose-dependent anti-proliferative effect on MM cell lines resistant to conventional therapy and by inhibition of angiogenesis in vivo. Thus, S-3-APG demonstrates superior in vivo anti-MM-activity compared to Thal and induces sustained complete tumor remission in vivo, without evidence of toxicity."

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[75] D'Amato RJ, Lentzsch S, Anderson KC, Rogers MS (Dec. 2001). *Mechanism of action of thalidomide and 3-aminothalidomide in multiple myeloma*. Semin. Oncol. 28 (6): 597–601. doi:10.1016/S0093-7754(01)90031-4. PMID 11740816.

142. As with D'Amato (2001), Lentzsch (2001) used idiosyncratic terminology. The article refers to pomalidomide by a trivial name, S-3-Amino-phthalimido-glutarimide (S-3APG). In chemistry, a trivial name is a non-systematic name, i.e., it does not follow the rules of a formal nomenclature system, such as the IUPAC. Using trivial names based on phthalimido-glutarimide for this group of compounds is atypical; the more uniform practice is to name these compounds according to IUPAC rules as substituted isoindole diones. One would therefore not appreciate that Lentzsch (2001) taught pomalidomide to treat multiple myeloma unless they were familiar with Dr. Lentzsch's use of a trivial name, "S-3-Amino-phthalimido-glutarimide," for the compound.

143. In April 2002, Lentzsch, D'Amato, and others published *S-3-Amino-phtahlimido-glutarimide Inhibits Angiogenesis and Growth of B-Cell Neoplasias in Mice*, which taught that pomalidomide was able to directly inhibit the proliferation of myeloma and that pomalidomide is "a powerful anti-myeloma and anti-B-cell-lymphoma agent that has both antiproliferative and antiangiogenic effects."[76] Again, Dr. Lentzsch and D'Amato used the idiosyncratic "S-3-Amino-phtahlimido-glutarimide" term to refer to pomalidomide.

144. In June 2002, Schey et al., Abstract #248, *A Phase I Study of an Immunomodulatory Thalidomide Analogue (CC4047) in Relapse/Refractory Multiple Myeloma,* Experimental Hematology (31st Annual Meeting of the International Society for Experimental Hematology held July 5-9, 2002), Volume 30, Issue 6, Supplement 1, 70-104, June 2002 ("Schey (June 2002)") disclosed pomalidomide for the treatment of multiple myeloma in humans.[77] Schey (June 2002) further

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[76] Suzanne Lentzsch , Michael S. Rogers, Richard LeBlanc, et al., *S-3-Amino-phthalimido Glutarimide Inhibits Angiogenesis and Growth of B-cell Neoplasias in Mice,* Cancer Rsch. 62 (8), 2300 - 05. PMID 11956087 (2002). .

[77] Abstract available for download at https://www.exphem.org/article/S0301-472X(02)00859-7/fulltext (last visited May 7, 2025).

disclosed "Phase I dose escalation study in relapsed/refractory multiple myeloma designed to identify the maximum tolerated dose (MTD) and evaluate the safety of CC-4047 when given orally for 4 weeks. Patients were enrolled in cohorts of 3 at each dose level: 1mg/day, 2mg/d, 5mg/d and 10mg/d." Schey (June 2002) established the maximum tolerated dose at 5 mg/day. Schey (June 2002) used the code name "CC-4047" to refer to pomalidomide,

145. In October 2002, Schey, S.A., *Thalidomide in the management of multiple myeloma,* Hematology 7(5):291-299 (October 2002) ("Schey (October 2002)") disclosed a phase I study of pomalidomide (again referred to in the study as CC-4047) in relapsed and refractory multiple myeloma.

146. Even though they use different terms and nomenclature, these studies published in the early 2000s teach pomalidomide to treat multiple myeloma. They are potentially invalidating prior art for anyone, including Celgene, who tried to patent pomalidomide as a compound or as a method to treat multiple myeloma. And indeed, many of these studies would become roadblocks for Celgene's Pomalyst patents.

147. Meanwhile, Celgene had continued publication of pomalidomide findings.

148. For example, on November 13, 2001, the PTO issued U.S. Patent No. 6,316,471 ("the '471 patent") entitled "Isoindolines, Method of Use, and Pharmaceutical Compositions" to Celgene. (Celgene would later list this patent in the Orange Book for Pomalyst). The '471 patent teaches the use of certain compounds including pomalidomide in the treatment of autoimmune diseases and cancers. The '471 patent also discloses that pomalidomide can be administered orally to reduce TNFα and can be administered in the form of a capsule or tablet containing from 1 to 100 mg of drug per unit dosage. The '471 patent discloses that decreasing TNFα constitutes a valuable therapeutic strategy to treat cancer. Claim 1 is directed to methods of treatment using pomalidomide and claim 16 is directed to the use of pomalidomide to treat an

oncogenic or cancerous condition. The '471 patent also teaches that pomalidomide and lenalidomide can be administered in combination with other active compounds, including antibiotics and steroids, such as dexamethasone.

149. When the '471 patent issued, Celgene announced that the patent claims covered "the use of ACTIMID™ (CDC 394), Celgene's next IMiD™, to treat cancer and inflammatory diseases both as a single agent and in combination with other therapies."[78] ACTIMID is pomalidomide.

10. Mid-2002: Celgene realizes Dr. D'Amato of Boston Children's Hospital is obtaining patents that would threaten any hopes Celgene had of monopolizing the market for pomalidomide (and lenalidomide).

150. From July 5, 2001, through June 11, 2002, Dr. D'Amato filed eight additional patent applications claiming methods of using lenalidomide (referred to as "6-amino EM-12") and pomalidomide (referred to as "3-amino thalidomide"). Although Dr. D'Amato used different nomenclature, "6-amino EM-12" and "3-amino thalidomide" refer to lenalidomide and pomalidomide, respectively.

Table X. 2001–2002 D'Amato Patent Applications

Application No	Filing Date	Title	Description
09/899,318	July 5, 2001	"Methods for the Inhibition of Angiogenesis with 6-amino EM-12"	Claims methods of using **lenalidomide**, including to treat undesired angiogenesis associated with blood-borne tumors.
10/015,252	Dec. 12, 2001	"Pharmaceutical composition of 6-amino EM-12"	Claims methods of using **lenalidomide** including to treat undesired angiogenesis that occurs in blood borne tumors.

[78] *See* Celgene Press Release (Nov. 13, 2001).

Application No	Filing Date	Title	Description
10/026,291[79]	Dec. 20, 2001	"Enantiomers Of 6-Amino EM-12 and Method of Use"	Claims methods of using **lenalidomide** including to treat angiogenesis and cancer.
10/167,531	June 11, 2002	"Method of Treating Disease Using 6-Amino EM-12"	Claims methods of using **lenalidomide** including to treat a blood or blood vessel disease (claim 106) that is an acute or chronic neoplastic disease of the bone marrow (claim 123) where the neoplastic disease is multiple myeloma (claim 124).
09/899,344	July 5, 2001	"Methods of the Inhibition of Angiogenesis with 3-Amino Thalidomide"	Claims methods of using **pomalidomide** to treat angiogenesis (claim 23, claim 31) including where the undesired angiogenesis is associated with blood-borne tumors (claim 99).
09/966,895	Sept. 28, 2001	"Methods and compositions for inhibition of angiogenesis"	Claims methods of using **pomalidomide** including to treat undesired angiogenesis that occurs in blood borne tumors.
10/166,539	June 10, 2002	"Methods of Treating Diseases Using 3-Amino Thalidomide"	Claims methods of using **pomalidomide** including to treat multiple myeloma.
10/020,391	Dec. 12, 2001	"Pharmaceutical Composition of 4-(amino)-2-(2,6-dioxo(3-piperidyl))-isoindoline 1,3-dione" [chemical name for pomalidomide]	Claims a pharmaceutical composition of **pomalidomide** to reduced undesired angiogenesis (claim 30), including where the angiogenesis is associated with blood borne tumors (claim 97).

[79] Note there is a similarly numbered D'Amato patent, the 5,712,291.

151. On October 31, 2001, the examiner issued a notice of allowance for the '318 D'Amato patent application, which claimed methods of using lenalidomide, including to treat undesired angiogenesis associated with blood-borne tumors.

152. On February 12, 2002, the examiner issued a notice of allowance for the '344 D'Amato patent application, which claims methods of using pomalidomide to treat angiogenesis, including angiogenesis associated with blood-borne tumors.

153. On April 16, 2002, the examiner issued a notice of allowance for the '391 D'Amato patent application, which claimed a pharmaceutical composition of pomalidomide to reduce undesired angiogenesis, including where the angiogenesis is associated with blood-borne tumors.

154. Previously, Celgene had suffered a near loss of its most important patent, the '517 compound patent, during reexamination because of earlier-in-time D'Amato patents (the '291, '990, and '327 patents). Now, in 2002, the patent examiner had issued notices of allowance for three new D'Amato patent applications (the '318, '344, and '391) while other D'Amato lenalidomide and pomalidomide patent applications were pending, including a patent application (the '539) specifically claiming pomalidomide for the treatment of multiple myeloma. D'Amato's acquisition of patents claiming methods of using lenalidomide and pomalidomide for the treatment of multiple myeloma and other blood-borne cancers threatened Celgene's ability to claim for itself a monopoly on the sale of these drugs.

155. On July 1, 2002, Celgene went on the offensive to clear the competitive landscape, transmitting a draft petition to the PTO asking the Group Director to the Office of the Commissioner, John Doll, to withdraw the already allowed '344 and '318 D'Amato patent

applications and to send D'Amato's pending '895 and '252 applications to quality review.[80] Celgene's petition was improper.[81] Celgene is also alleged to have called the Group Director directly to block the D'Amato patent applications.[82]

156. Celgene argued that the specific compounds claimed in the '318 and '252 applications ("6-amino-EM-12" or lenalidomide) and the '344 application ("3-amino-thalidomide" or pomalidomide) were not specifically disclosed in the provisional patent application and thus lacked written description support under section 112. Referring to the earlier '517 reexamination, Celgene represented that the PTO had previously found the "D'Amato Patents insufficient to anticipate or render obvious the '517 claims to [lenalidomide] *per se* or to methods employing [pomalidomide]."[83] This was false. During the reexamination, the examiner held the '517 unpatentable in light of the earlier D'Amato patents and expressly rejected Celgene's argument that the D'Amato patents did not adequately disclose the compounds at issue. Celgene omitted to disclose that the reexamination examiner rejected the issued claims of Celgene's '517 patent for these reasons, and only permitted it to reissue when Celgene submitted the false declaration of Dr. Stirling and accompanying Remarks by Celgene's agent Bruce Collins.

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[80] *See* Petition at 11, *Children's Med. Ctr. Corp. v. Celgene Corp.*, 13-cv-11573 (D. Mass. Sept. 4, 2015), ECF No. 92-5 (the petition was filed in the royalty dispute docket as an exhibit).Page numbers correspond to ECF document.

[81] Off. Gaz. Pat & Trademark Office (April 22, 2003), available at https://www.uspto.gov/news/og/2003/week16/patoppo.htm (last accessed May 15, 2025).

[82] *See* Complaint at 14, *Children's Med. Ctr. Corp. v . Celgene Corp.*, 13-cv-11573 (D. Mass. Aug. 4, 2015), ECF 85-4. The '539 (pomalidomide to treat MM) had not yet been allowed when Celgene began to interfere, but the same events played out there.

[83] *See* Petition at 6-7, *Children's Med. Ctr. Corp. v. Celgene Corp.*, 13-cv-11573 (D. Mass. Sept. 4, 2015), ECF No. 92-5.

157. On July 29, 2002, just a few weeks after Celgene submitted its false and misleading petition to the PTO, Group Director John Doll withdrew the allowances for the '318, '344, and '391 D'Amato patent applications pending further inquiry.

158. On September 3, 2002, the PTO conducted an interview regarding the pending D'Amato patent applications that included at least four PTO representatives: two Primary Examiners (J. Reamer and J. Goldberg), a Supervisory Patent Examiner (M.A. Seidel), and a Specialist from Quality Control in the Patent Office (R. Hill). Attorney Jeffrey Arnold, attorney Robert Richards, participated for Children's (D'Amato's assignee) and EntreMed (Children's commercial development partner and licensee of D'Amato patent applications).

159. Shortly after the interview, the PTO began issuing (or reissuing) notices of allowance for several D'Amato patent applications claiming methods of using pomalidomide, including the '344 application (re-allowed October 21, 2002), the '391 application (re-allowed November 6, 2002), and the '539 application (allowed December 13, 2002). The '539 application (which had been published a few weeks earlier, on October 31, 2002) expressly claimed methods of using pomalidomide to treat multiple myeloma.

160. The issuance of patents to D'Amato for pomalidomide (and lenalidomide) to treat multiple myeloma and other blood-borne cancers posed an existential threat to Celgene's sales of thalidomide analogs. Celgene's response was to sue Children's development partner, EntreMed, and the PTO.

161. On November 6, 2002, Celgene filed provisional patent application no. 60/424,600, the provisional application that would eventually lead to the method of treatment patents at issue in this case.

162. Then, on November 19, 2002, Celgene sued James E. Rogan, in his official capacity as Under Secretary of Commerce for Intellectual Property and Director of the PTO,

and EntreMed seeking, *inter alia*, "preliminary and permanent injunctions directing defendant Rogan to withdraw" the '344 and '391 applications from issue and requiring EntreMed to file petitions for withdrawal.[84] In this litigation, Celgene was represented by Anthony Insogna's law firm at the time, Pennie & Edmonds. Faced with Celgene's relentless onslaught, Children's partner EntreMed hit back.

163. On November 21, 2002, EntreMed sued Celgene for violating the antitrust laws by unlawfully blocking EntreMed's drug development efforts, alleging: "rather than compete on the merits, Celgene has chosen to engage in conduct illegal under the antitrust laws, designed to inhibit or eliminate competition by EntreMed in the development of amino-thalidomide drugs. Such conduct includes the acquisition of invalid patents for Celgene's aminothalidomide drugs, the use of such patents to prevent EntreMed from acquiring valid patent protection for its 3-amino thalidomide drug, and the filing of baseless litigation against EntreMed regarding patent applications covering its 3-amino thalidomide drug."[85]

164. EntreMed further alleged that Celgene had "embarked on an intentional campaign to harm EntreMed" and "to monopolize the market for aminothalidomide drugs by preventing innovation competition between EntreMed and Celgene."[86]

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[84] *Celgene v. Rogan, et al.,* No. 02-cv-02277 (D.D.C.), Complaint, filed Nov. 19, 2022, at p.13 (ECF No. 1). The '539 application was not listed in Celgene's original complaint against the PTO and EntreMed, possibly because the examiner had not yet issued a notice of allowance as to that patent (though it would do so a few weeks later).

[85] *EntreMed v. Celgene*, No. 02-cv-03787 (D. Md.), ECF No. 1 (Complaint, filed Nov. 21, 2022) at ¶¶ 10–11.

[86] *Id.* at ¶ 13.

165. Through all this tumult, one fact stands: D'Amato obtained a patent claiming pomalidomide to treatment multiple myeloma *years* before Celgene filed its own patent application claiming the same invention.[87]

166. But in 2002, EntreMed was a fledging clinical stage biopharmaceutical company with fewer than 60 employees (more than half of whom were in R&D) on the verge of delisting due to capital constraints. Celgene, on the other hand, was a large corporation with over $135 million in annual revenue. Having failed to block the patents from issuing to D'Amato, and hit with allegations of pervasive anticompetitive conduct, Celgene's only hope to salvage its would-be billion-dollar monopoly was to buy and bury D'Amato's IP.

11. December 2002: Celgene's lawsuit was short-lived, but gave it the leverage it needed to extract the rights to D'Amato's IP from its much smaller rival EntreMed.

167. On December 31, 2002, EntreMed and Celgene settled and entered into a three-way licensing agreement that included Children's Hospital. The license agreement specifically had definitions for "Amino Thalidomide" using the chemical structure diagram for pomalidomide (and "Revimid" using the chemical structure diagram for lenalidomide). In exchange for future royalties, "Children's would grant Celgene an exclusive license to patents and patent applications . . . in consideration of Celgene's payment of specified payments, including but not limited to running royalties on Amino Thalidomide and Revlimid products."[88]

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[87] Patent Application No. 12/229,074 (filed Aug. 19, 2008).

[88] The terms of the December 31, 2002 licensing agreement (a three-way agreement between EntreMed, Children's, and Celgene) (the "December 31, 2002 Exclusive License Agreement") were disclosed in subsequent litigation filed by Children's against Celgene in 2013 arising out of a royalties dispute. *See Children's Medical Center Corp. v. Celgene,* 13-cv-11573 (D. Mass.), Complaint (ECF 1-1, filed July 2, 2013) at ¶6, describing the December 31, 2002 Exclusive License Agreement (ECF 85-4) at ¶¶4.1 and 4.3.

168. Under the arrangement, Celgene became the exclusive licensee for a broad portfolio of pending patent applications and published patents—all of which had priority dates before November of 2002—that disclosed uses and properties of thalidomide and thalidomide analog compounds, including "Amino Thalidomide", i.e., pomalidomide.

169. By acquiring D'Amato's IP, Celgene acquired the rights to patents claiming pomalidomide to treat multiple myeloma and other blood borne cancers. But D'Amato's '539 patent, claiming pomalidomide to treat multiple myeloma, was allowed in 2002 and would expire in or before 2022. In contrast, Celgene did not apply for its own patent claiming pomalidomide to treat multiple myeloma (the '262 patent) until 2008, potentially gaining it additional years of market exclusivity.

170. Because patent prosecutions are *ex parte* and the PTO relies on the applicant to disclose all relevant information, acquiring the broad patent portfolio in the December 31, 2002, Exclusive Licensing Agreement reduced Celgene's risk that any of the earlier in time D'Amato patents would be asserted against Celgene as prior art by a third party.

B. November 2002—Celgene begins fraudulent pursuit of method of use patents for pomalidomide.

171. Concurrently with its litigation against EntreMed, and the settlement agreement shortly thereafter, Celgene began seeking its own method of use patents.

172. On November 6, 2002, Celgene filed provisional patent application no. 60/424,600 generally claiming methods of using immunomodulatory compounds to treat various cancers, and specially claiming lenalidomide (identified by its chemical name, 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione, and by its then-used commercial name, Revlimid) and pomalidomide, (identified by its chemical name, 4-(amino)-2-(2,6-dioxo(3-

piperidyl))-isoindoline-1,3-dione, and by its then-commercial name, Actimid[89]) for treating refractory or relapsed multiple myeloma.[90] The application also reported the results of Phase I clinical trials for both compounds, trials that had been shaped by and based on the significant, reported scientific research over the prior two decades.

173. Starting from this November 6, 2002, application,[91] Celgene, along with co-conspirators Insogna and Zeldis, would seek a series of patents for methods of using lenalidomide and pomalidomide for the treatment of multiple myeloma. In doing so, they repeatedly misrepresented known material facts, and omitted known material facts, to the U.S. patent office.

174. All of Celgene's method of treatment patents at issue in this case (the 8,198,262, 8,673,939, and 8,735,428) are derived from the November 2002 provisional application. This means that all information publicly disclosed *before* November 6, 2002, including all of the patents, patent applications, and scientific articles described above, are prior art against which the novelty/inventiveness of these new method-of-treatment claims would be judged.

175. The family of applications and patents that issued in this family (and that were asserted in patent infringement litigation against Pomalyst ANDA filers) is illustrated by the

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[89] Also referred to as CC-4047.

[90] "Refractory myeloma" means that the cancer is not responsive to or progresses within 60 days of the last line of therapy. "Relapsed myeloma" is previously treated myeloma that has progressed after previous therapy and needs new therapy. Parva Bhatt, Colin Kloock, & Raymond Comenzo, *Relapsed/Refractory Multiple Myeloma: A Review of Available Therapies and Clinical Scenarios Encountered in Myeloma Relapse*, 30 Current Oncology 2322, 2322 (2023).

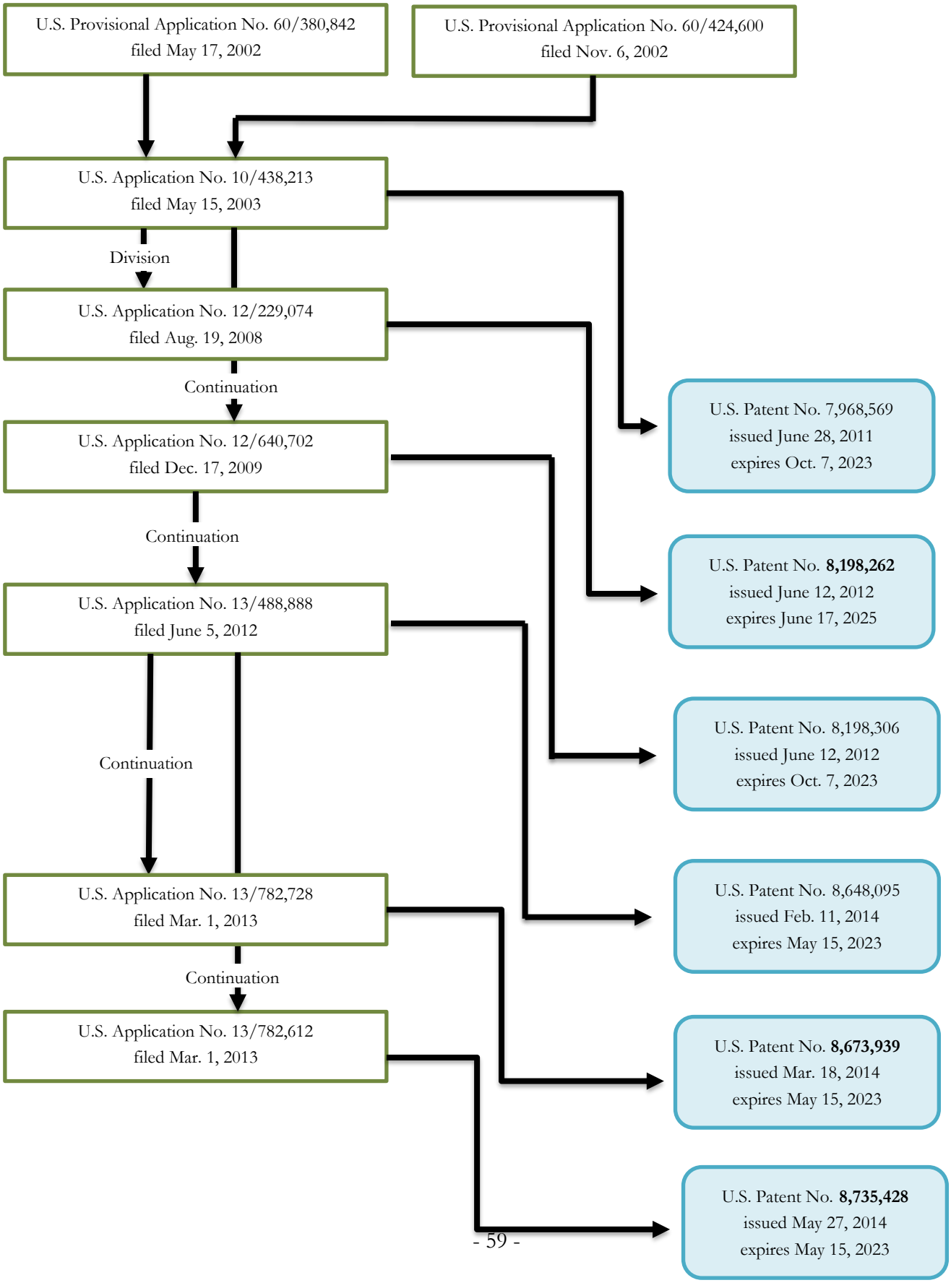
[91] An earlier provisional application had been filed in May 2002 relating to treatments combining thalidomide analogs with large molecule proteins, and that application is sometimes attributed as being within this patent family. Presumably because that application related to treatments combining the analogs with the proteins, and not the analog alone, the November 6, 2002, application was treated as the relevant priority date by the parties during the subsequent patent litigation. We do the same here.

following diagram of patent applications and issued patents.[92] The three relevant, fraudulently acquired, pomalidomide method of treatment patents are the '262, the '3939[93], and the '428.

[92] "Expires" represents the patent expiration date exclusive of pediatric exclusivity ("PED"). The following patents have PEDs exclusivity: 8,198,262 (12/17/2023), 8,673,939 (11/15/2023), and 8,735,428 (11/15/2023).

[93] We refer to this patent as the '3939 as there is another Celgene (formulation patent 10,555,939) that ends in the same three digits. We refer to the formulation patent (discussed *infra*) as the '5939.

THALIDOMIDE ANALOG METHOD OF USE PATENT TREE



176. On December 9, 2002, Celgene obtained approval under an investigational new drug application (IND) to conduct tests using pomalidomide.

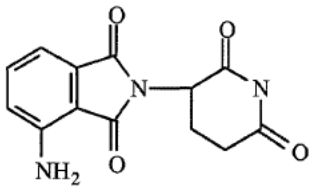
177. On May 15, 2003, Celgene filed patent application no. 10/438,213, which taught lenalidomide and its use for treating cancer, including multiple myeloma. This application would eventually result in the 7,968,569, which claimed a method of treating multiple myeloma through cyclical dosing of lenalidomide, *i.e.,* 21 consecutive days of administration followed by 7 days of rest, in combination with dexamethasone.

C. 2003: Celgene and Insogna dismantled D'Amato's patent portfolio disclosing pomalidomide.

178. While Celgene was building up its own pomalidomide patent portfolio, Celgene was taking steps to bury the D'Amato pomalidomide patents and patent applications for which it had purchased licenses from Children's Hospital and EntreMed.

179. Some of D'Amato's patents in the licensing agreement claimed the compound pomalidomide and its use in treating undesired angiogenesis, including U.S. Patent No. 7,153,867 (the '867) and U.S. Patent applications 09/899,344 (the '344 application), 09/966,895 (the '895 application), 10/166,539 (the '539 application), and 10/020,391 (the '391 application).

180. In the licensed patents and in his other published work, D'Amato routinely used the term "3-aminothalidomide" to refer to pomalidomide. For example, the '391 amended application claimed in claim 30: "A pharmaceutical composition compromising…3-amino thalidomide having the formula



…to reduce the effects of an angiogenesis-mediated disease." The compound depicted is pomalidomide.

181. Celgene licensed D'Amato's patents and pending patent applications, and Anthony Insogna took over as power of attorney for D'Amato patent applications, including the '344, '895, '539, and '391 patent applications.

182. On February 11, 2003, less than six weeks after Celgene acquired the rights to D'Amato's IP, the '539 patent application, which had already been allowed, was expressly abandoned. The petition for abandonment states: "The Issue Fee for the above captioned application was paid on December 23, 2002. Applicants respectfully request that the application be withdrawn from issue after payment of the Issue Fee. . . . Applicants further request that this petition be acted upon with dispatch so as to avoid inadvertent issuance of a patent from the instant application."[94]

183. By the end of 2003, all four D'Amato patent applications that claimed pharmaceutical compositions and methods of using pomalidomide had been abandoned, even though some (like the '539) had already been allowed.

184. Insogna's conduct during these proceedings demonstrated that he knew that D'Amato used the atypical term "3 aminothalidomide" to refer to pomalidomide. For example, during his prosecution of D'Amato's '391 application, Insogna submitted a signed declaration stating that "3-aminothalidomide" was in fact pomalidomide.[95] (Although Insogna was well

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[94] Patent Application No. 10/166,539, Petition Under 37 C.F.R. §1.313(c)(3) for Withdrawal of Application from Issue After Payment of Issue Fee, dated Feb. 11, 2003, at 1 ('539 application file wrapper at p. 337).

[95] Celgene Response to PTO after Non-Final Action, U.S. Patent Application 10/020,391, 13, 20 (July 11, 2003).

aware of these facts, he would later conceal that "3-aminothalidomide," as used in a prior art reference written by D'Amato, referred to pomalidomide and indeed taught pomalidomide to treat multiple myeloma, the very invention for which Celgene was then seeking patent protection).

185. To shore up its defenses, Celgene went so far as to re-write one patent, the 5,712,291, that had been issued to D'Amato in January 1998. The '291 patent (not to be confused with the '291 patent application) claimed a method of using pomalidomide to treat angiogenesis. After obtaining rights to this patent (pursuant to the December 2002 Exclusive Licensing Agreement), Celgene's attorney Thomas Friebel of Jones Day filed an application to remove pomalidomide from the '291 patent, claiming the inclusion of pomalidomide in this patent was an "error" (the same argument Celgene raised and the PTO rejected way back during the reexamination of Celgene's own '517 patent). The PTO eventually assented to Celgene's request.

D. 2005-2006: FDA approved Celgene's blockbuster drugs Thalomid and Revlimid for treating multiple myeloma.

186. On December 27, 2005, the FDA approved lenalidomide, under the brand name Revlimid, for use in the treatment of patients with myelodysplastic syndromes,[96] a group of disorders that occur when blood-forming cells in bone marrow become abnormal (a condition considered a type of cancer).

[96] It was approved "for the treatment of patients with transfusion dependent anemia due to low or intermediate-1 risk myelodysplastic syndromes associated with a deletion 5 q cytogenetic abnormality with or without additional cytogenetic abnormalities." *See* Dec. 27, 2005 Final Approval Letter, available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2005/021880rev2.pdf (last accessed Sept.4, 2023).

187. On May 25, 2006, the FDA approved Celgene's new drug application for the use of thalidomide capsules, 50 mg, 100 mg, and 200 mg, under the brand name Thalomid, for the treatment of patients with newly diagnosed multiple myeloma. For treatment of multiple myeloma, the approved label stated that thalidomide is administered in combination with dexamethasone 40 mg.

188. On June 29, 2006, the FDA approved Celgene's NDA for lenalidomide 5 mg, 10 mg, 15 mg, and 25 mg capsules, under the brand name Revlimid, in combination with dexamethasone for the treatment of multiple myeloma patients who had received one prior therapy. The recommended starting dosage was 25 mg daily on days 1-21 of a 28-day repeated cycle with dexamethasone 40 mg. (Lenalidomide 5 mg and 10 mg capsules had been approved approximately six months earlier for treatment of certain patients with transfusion-dependent anemia due to myelodysplastic syndromes).

E. 2008-2012: Celgene continued fraudulent pursuit of method of use patents for pomalidomide.

1. August 2008—Celgene filed the application for the first of its pomalidomide method of use patents, which it obtained by fraud.

189. On August 19, 2008, Celgene, along with co-conspirators Insogna and Zeldis, filed patent application 12/229,074 claiming methods of treating multiple myeloma with pomalidomide (1 mg to 4 mg), with and without using dexamethasone and a cyclic dosing regimen. (This application would eventually lead to the incorrect issuance of the 8,198,262 method of treatment patent.).

190. The '262 patent applicant was inventor Zeldis. The attorney who prosecuted the application that led to the '262 patent was Insogna.

191. As part of the initial application, Celgene and its agents Zeldis and Insogna filed a "List of References Cited by Applicant," also referred to as the Initial Disclosure Statement (or

IDS). Celgene's IDS listed 294 U.S. patent documents, foreign patent documents, and other articles and references (a list that would eventually grow to 311 documents). Although the IDS lists the '539 patent application (under an alternate document number, 2002/0161023), the title of the patent application is "Method of Treating Diseases with 3 Amino Thalidomide." The document does not reflect, and Celgene did not disclose, that the PTO had, six years earlier, allowed a patent to D'Amato for the claimed invention or that the claimed invention was for the use of pomalidomide to treat multiple myeloma.

192. On June 24, 2010, the patent examiner issued an office action rejecting the claims based on obviousness and double patenting. For the obviousness rejection, the office relied on a combination of the '517, Davies (2001), and either the 6,555,554 or 6,281,230 to conclude that it would have been obvious to use the thalidomide analog pomalidomide (referred in the action as ACTIMID) in the cyclical treatment of multiple myeloma as it was a known effective agent in decreasing TNFα and that a skilled artisan would adjust dose depending on the level of disease and the potency of the drug. The double patenting objections also relied on the '517 and Davies (2001) to show that there would be double patenting over a series of five patents that already issued in Celgene's favor.

193. While the office action rejected the claims, it did so on a basis that required the *combined* teaching of the three specific references. The patent examiner was under the misimpression that neither the '517 nor Davies (2001) expressly taught pomalidomide, and that the '554/'230 did not expressly teach multiple myeloma. Nor did the patent examiner cite other earlier scientific literature or patents showing the treatment of multiple myeloma with pomalidomide itself. Rather, the examiner concluded—based only on the three references—that the references taken together showed the use of thalidomide and its analogs act directly on multiple myeloma cells, and that one of ordinary skill in the art would have been motivated by

the reasonable expectation that the thalidomide analog pomalidomide (which is also effective in decreasing TNFα) would also be effective in the treatment of multiple myeloma since the decrease in TNFα provided the rationale for treating the disease with thalidomide.

194. On December 23, 2010, Insogna, on behalf of Celgene, submitted an amendment. In the amendment, Celgene, along with co-conspirators Insogna and Zeldis, made materially false and misleading statements intended to overcome the examiner's objections.

195. *Falsity regarding the '517 patent*. Celgene's response to the examiner's citation to the '517 was false and misleading. In the office action, the examiner made two mistakes about the '517, one that helped Celgene's efforts to get the patent and one that hurt those efforts. First, the examiner mistakenly attributed to the '517 specific statements of the treatment of multiple myeloma with thalidomide and dexamethasone.[97] This information was publicly disclosed, but in a different reference (Kyle (2001)), not in the '517. The second, and more important, error by the examiner was to state (twice) that the '517 "did not expressly teach ACTIMID [pomalidomide]."[98] That was incorrect. The '517 claims a method of reducing undesirable levels of TNFα where the compound is pomalidomide, which the '517 discloses is "a valuable therapeutic strategy for the treatment of. . . . cancer. . . ." The '517 specifically disclosed pomalidomide and its use to reduce TNFα.

196. In its response, Celgene argued that the '517 did not have the material in it that the examiner had mistakenly reported (i.e., the treatment of multiple myeloma with thalidomide and dexamethasone). (Celgene did not volunteer that this disclosure *did* appear in a different

[97] June 24, 2010 Detail Action at p. 5 ('262 application file wrapper at p. 105)

[98] June 24, 2010 Detail Action at pp. 5, 7 ('262 application file wrapper at pp. 105, 107).

reference (Kyle 2001)),[99] but the examiner apparently figured this out subsequently on his own.[100]) As to the second, more important, mistake made by the examiner, , i.e., whether the '517 patent expressly taught pomalidomide, Celgene not only refrained from *correcting* the mistake, Celgene *amplified* it, stating: "The PTO admits that the primary reference does not teach ACTIMID (page 5 of the Action)."[101] Celgene knew its statement was false.

197. Celgene is the owner of the '517 patent, the compound patent for Celgene's multi-billion dollar a year drug Revlimid. The '262 patent applicant, Zeldis, and his attorney, Insogna, both knew the '517 patent specifically disclosed pomalidomide, and they knew that the '517 claimed a method of using pomalidomide to reduce TNFα and taught that reduction of TNFα was a means of treating cancer. They also knew of the potential for confusion on the part of the patent examiner on the subject (given different ways to refer to pomalidomide). Yet Celgene (along with co-conspirators Insogna and Zeldis) fraudulently withheld and omitted the true import of the '517 patent on patentability, and did so in order to obtain the '262 patent.

198. Insogna knew that the '517 taught pomalidomide. By this time, Insogna had been representing Celgene for years and was intimately knowledgeable on all aspects of Celgene's thalidomide analog portfolio. He had direct work on the '517 patent itself. At the time, the '517 patent was (and would continue to be) the cornerstone of Celgene's Revlimid empire, raking in profits of nearly $2.5 billion on the drug in 2010. Yet Insogna nonetheless reiterated and implicitly reaffirmed the patent examiner's mistaken belief that the '517 did not teach pomalidomide.

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[99] *See generally* Celgene's December 23, 2010 Remarks ('262 application file wrapper at pp. 131-139).

[100] *See* August 9, 2011 Non-Final Rejection at p. 3 ('262 application file wrapper at p. 187).

[101] December 23, 2010 Remarks at p. 7 ('262 application file wrapper at p. 132).

199. Zeldis knew that the '517 taught pomalidomide. Zeldis had been an executive at Celgene since 1997, specifically serving as Chief Medical Officer since 1999. As a senior executive, scientist, and inventor at Celgene, Zeldis understood what the '517, Celgene's most important patent, claimed, including teaching pomalidomide.

200. The only logical inference from the fact that Celgene did, in fact, choose to comment on the contents of the '517 and yet chose not to comment on the known aspects of the '517 that render claims of the '262 patent unpatentable is that Celgene (along with co-conspirators Insogna and Zeldis) made that statement in support of patentability with the intention that the examiner rely on it and issue the patent.

201. Celgene, along with co-conspirators Insogna and Zeldis, exploited the examiner's incorrect belief that the '517 did not teach pomalidomide by repeating it and failing to correct it, thus reinforcing the examiner's incorrect understanding. Celgene wrote: "The PTO admits that the primary reference [the '517] does not teach ACTIMID (page 5 of the Action). Thus, the primary reference does not direct the skilled person to use the recited compound in the treatment of multiple myeloma." This is incorrect. Celgene (along with co-conspirators Insogna and Zeldis) knew that the '517 patent *did* teach pomalidomide.

202. Celgene's falsehoods about the '517, which it never corrected, conflict with its duties of good faith, candor, and disclosure (*see e.g.* ¶¶ 46-49, 55, *supra*), and is part of a pattern of hiding information to deceive and mislead the examiner.

203. *Falsity regarding Davies (2001).* Celgene (along with co-conspirators Insogna and Zeldis) also repeated and perpetuated the examiner's mistaken belief that Davies did not teach pomalidomide. Davies (2001) disclosed that thalidomide and the three immunomodulatory drugs studied (referred to as IMiD1, IMiD2, and IMiD3) can act directly on multiple myeloma cells and are useful in relapsed/refractory disease. Celgene coined the term "immunomodulatory

drugs" or "IMiDs" to refer to its thalidomide analogue drugs, most prominently pomalidomide and lenalidomide. Davies (2001) did not identify the three IMiDs by chemical structure or by chemical name, a fact that Celgene capitalized on to mislead the examiner into believing that pomalidomide was not one of the drugs studied in Davies (2001). This was false. Pomalidomide has been one of Celgene's two most important IMiDs since its research into thalidomide analogues began (the other being lenalidomide). Davies' teachings are about pomalidomide. Celgene parrots the examiner's incorrect belief ("the Office admits that [Davies] does not teach ACTIMID."). Celgene's agents knew this was false, as two of Celgene's senior scientists, George Muller and David Stirling, were involved in the Davies study and are named authors on it. Celgene never corrected this false statement.

204. *Falsity regarding D'Amato prior art references*. Celgene (along with co-conspirators Insogna and Zeldis) failed to disclose that the PTO had already issued a patent to D'Amato claiming pomalidomide to treat multiple myeloma and that other D'Amato references, including D'Amato (2001), taught pomalidomide for the treatment of multiple myeloma.

205. During the prosecution that led to the '262 patent, the patent examiner focused on whether the prior art taught pomalidomide or taught treating multiple myeloma. Over the course of the prosecution of the '262 patent, the examiner never discussed the patent that had already been allowed to D'Amato for pomalidomide to treat multiple myeloma (the '539 patent application). He also did not discuss other D'Amato prior art, including D'Amato (2001), which teaches not just one, but both, of these critical points, *i.e.,* the use of pomalidomide to treat multiple myeloma. The D'Amato patent application and article consistently refer to pomalidomide by the idiosyncratic term "3 aminothalidomide."

206. Celgene, along with co-conspirators Insogna and Zeldis, knew that the term 3 aminothalidomide referred to pomalidomide. *See* Section X, *supra.* In response to the examiner's

initial rejection, they engaged in a misdirection, arguing that two other patents, the '230 and '554, did not teach the use of pomalidomide to treat cancer. But in making these arguments, Insogna and Zeldis concealed that the patent that had been allowed to D'Amato (the '539 patent application) and D'Amato 2001 *did* specifically teach the use of pomalidomide to treat multiple myeloma. While the representations Celgene made were technically true as to the '230 and '554, Celgene knowingly and willfully misrepresented the critical role of the '539.

207. Celgene, along with co-conspirators Insogna and Zeldis, knew this *material* information, but fraudulently omitted the truth about the '539 patent application and D'Amato (2001) to the examiner. While both the '539 patent application and D'Amato (2001) include diagrams of pomalidomide, the import of the references was not apparent. Zeldis and Insogna were knowledgeable about D'Amato's research involving thalidomide compounds, including pomalidomide, and knew the '539 patent application and D'Amato (2001) taught pomalidomide to treat multiple myeloma. They deliberately omitted this information from the examiner.

208. Insogna knew that the '539 patent application and D'Amato (2001) used the name 3-aminothalidomide to refer to pomalidomide. Pursuant to the December 31, 2002 Exclusive License Agreement, Celgene had licensed more than 75 patents and patent applications on which D'Amato was an inventor or co-inventor.[102] In six of those patents and patent applications, D'Amato repeatedly used "3 aminothalidomide" to refer to pomalidomide, including labeling diagrams of pomalidomide as "3 aminothalidomide."[103]

209. Following the December 31, 2002 Exclusive License Agreement, Insogna was designated to receive notice under the agreement, and he took over the prosecution and

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[102] December 31, 2002 Exclusive License Agreement at ¶7.1(d) and Appendix A.

[103] *See e.g.,* U.S. Patent Applications 10/020,391 and 09/966,895.

management of the D'Amato patent and patent application portfolio.[104] On March 18, 2003, he became the attorney of record for the '539 patent application with all future correspondence regarding that patent application to be directed to his attention:[105]

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Anthony M. Insogna, Esq.
PENNIE & EDMONDS LLP
1155 Avenue of the Americas
New York, New York 10036-2711
(212) 790-9090

210. More generally, in his role managing (and abandoning) D'Amato's patents and patent applications, Insogna demonstrated awareness that D'Amato used "3 aminothalidomide" to refer to pomalidomide. For example, during the prosecution of the '391 D'Amato patent application, Insogna filed revised claim language stating that the compound D'Amato referred to as "3-aminothalidomide" was "4-(amino)-2-(2,6-dioxo(3-piperidyl))-isoindoline- 1,3-dione," the name Celgene and Insogna regularly used to refer to pomalidomide, demonstrating Insogna was well aware D'Amato used "3 aminothalidomide" to refer to pomalidomide. From the outset of the patent prosecution, Celgene knew, the examiner was focused on whether any *combination* of the prior art references taught pomalidomide to treat multiple myeloma. Indeed, the initial rejection was based on the belief that:

[104] Given his role in prosecuting D'Amato's '391 patent application, among other patents, for Celgene, generic company Hetero subsequently sought to depose Insogna in Celgene's patent infringement litigation against Hetero. In opposing Insogna's motion to quash the subpoena, Hetero explained that Insogna's prosecution of D'Amato's patents involved "expressly abandon[ing] them, even after one had received a notice of allowance from the patent office." Hetero's Opposition to Mot. To Quash at 11, *In re Subpoena on Third Parties Anthony Insogna and David Gay*, No. 3:19-cv-01589-LAB-AHG (S.D. Cal. Oct. 17, 2019), ECF No. 9.

[105] *See* Revocation and Power of Attorney, at 2 ('539 application file wrapper at pp. 348-349).

a) The ’517 taught thalidomide (but not pomalidomide) and dexamethasone to treat multiple myeloma.

b) Davies (2001) taught that thalidomide and its analogues can act directly on multiple myeloma cells.

c) The ’554 taught pomalidomide to treat cancerous conditions.

211. Celgene’s submission refuting the examiner’s findings repeats the errors that helped Celgene, while failing to mention the fact that a patent for the claimed invention had already issued to another inventor years earlier; or that D’Amato (2001), standing alone, teaches pomalidomide to treat multiple myeloma. This was a violation of Celgene’s duties of good faith and candor.

212. Celgene’s only mention of D’Amato (2001) during the nearly 4-year prosecution of the ’262 patent was in the list of initial disclosures, where Celgene buried the article among nearly 300 other references. Celgene knew that the title of the article (“Mechanisms of action of thalidomide and 3-aminothalidomide in multiple myeloma”) referred to pomalidomide by an idiosyncratic term that the examiner was unlikely to recognize; and Celgene did not submit the article to the examiner. The examiner never mentions D’Amato (2001) during the ’262 patent prosecution, even though the reference was a closer prior art reference as compared to the references the examiner cites in his analysis.

213. In short, during the prosecution of the ’262 patent, including in the December 23, 2010 amendment and response, Celgene, along with co-conspirators Insogna and Zeldis, deceived the examiner into withdrawing prior rejections by misleading the examiner and concealing from him a wealth of prior art of which they were aware and which they knew would render the application not allowable, including the ’539 patent application and D’Amato (2001).

214. The ruse worked. On August 9, 2011, the patent examiner, relying upon the misrepresentations by Celgene (with co-conspirators Insogna and Zeldis), withdrew the prior rejections, including his objections based on the '517. In the office action, the examiner made no further mention of the '517 as an objection to obviousness, nor as a basis to reject the claims for double patenting with the five patents in the '517 patent tree.

215. Instead, in the August 2011 office action, the examiner again rejected all claims, this time relying on Kyle (2001) (the correct reference for the material regarding cyclical dosing of thalidomide analogs with dexamethasone previously attributed to the '517) and several other references (Davies (2001), Corral (1999), Muller (1999), and the '554/'230). The examiner wrote it "would have been obvious to one having ordinary skill in the art at the time the invention was made to treat [multiple myeloma] with pomalidomide as suggested by Kyle[,] Davies, Corral and Muller by administering pomalidomide in a tablet or capsule . . . ."

216. On December 20, 2011, Celgene, again along with co-conspirators Insogna and Zeldis, filed an amendment and response that, made at least four further false statements and material omissions with the intent of overcoming the examiner's objections.

217. *First, falsity regarding treatment of multiple myeloma with pomalidomide*. In the December 20, 2011 remarks, Celgene stated: "there is no suggestion in the art that pomalidomide is effective to treat multiple myeloma. . . ."[106] Celgene, Zeldis, and Insogna omitted to disclose that a patent claiming pomalidomide to treat multiple myeloma had already been issued to D'Amato. They also did not disclose the lengths to which Celgene and its agents went to block that patent. *See supra.* Celgene, Zeldis, and Insogna also omitted to disclose that D'Amato (2001), Lentzsch (2001), Lentzsch (2002), Schey (June 2002), and Schey (October 2002), specifically taught

[106] *See* December 20, 2011 amendment and response at 6.

pomalidomide for the treatment of multiple myeloma and/or relapsed/refractory multiple myeloma. Although a subset of these articles were listed (by title only) in Celgene's voluminous IDS, the article titles used idiosyncratic terms and code names to refer to pomalidomide that obscured the teachings of these references. But Celgene, Zeldis, and Insogna knew the meaning of these terms. These references are much closer prior art to the claimed invention, but the examiner never mentions any of them during the prosecution of the '262 patent.

218. *Second, falsity regarding relative power.* In the December 20, 2011 Remarks, Celgene made misleading statements and material omissions suggesting that the use of one thalidomide compound over another had not been publicly disclosed previously, including falsely asserting that Davies (2001) did not teach that pomalidomide was more effective than thalidomide in the treatment of multiple myeloma: "Davies does not teach or suggest that pomalidomide is more effective than thalidomide in the treatment of multiple myeloma. There would be no basis in Davies to select one compound over the other."[107] This was false. Davies (2001) taught that new thalidomide analogs, including lenalidomide and pomalidomide (referred to in the article as "IMiDs") are 50,000 times more potent in inhibiting TNFα as compared to thalidomide.

219. Celgene, Zeldis, and Insogna also omitted to disclose that the relative power of pomalidomide to reduce TNFα levels was previously publicly disclosed, including by Celgene. For example, as part of the 1998-1999 reexamination of the '517 Revlimid patent, Celgene submitted data to the patent office showing that pomalidomide was purportedly 10,000-fold more active than the comparator compound selected by Celgene. Specifically, on February 25, 1999, Bruce Collins, counsel for Celgene, submitted the signed declaration of Celgene senior executive David Stirling (also dated February 25, 1999), which stated, "I conclude that

[107] *See* December 20, 2011 amendment and response at 7.

Compound 2 is >10,000 fold more active than Compound 1 in this primary human cell-based assay." "Compound 2" is identified in the Stirling Declaration (by structural diagram[108]) as pomalidomide.

220. Use of pomalidomide over thalidomide was also publicly disclosed in the D'Amato (2001) reference (published in the December 2001 issue of Seminars in Oncology), which states: "If thalidomide blocks angiogenesis by regulating TNF-α, one would expect 3-aminothalidomide [pomalidomide] to be a more effective angiogenesis inhibitor than thalidomide, since the former compound [pomalidomide] is a 15,000-fold more potent TNF-α inhibitor than thalidomide."[109]

221. *Third, falsity regarding treatment for refractory patients*. In the December 20, 2011 Remarks, Celgene stated: "[t]hese publications clearly demonstrate unexpected results of the claimed therapy for relapsed or refractory multiple myeloma."[110] That was knowingly false, as there was nothing surprising about the fact that the more potent thalidomide analog, pomalidomide, would be used where the multiple myeloma patient had become relapsed or refractory to less potent analogs such as thalidomide and lenalidomide. The prior art, including Schey (June 2002), specifically taught pomalidomide for the treatment of relapsed and refractory multiple myeloma.

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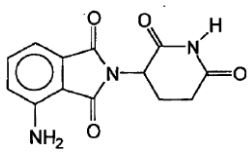
[108] *See* '517 reexamination, Stirling Declaration at ¶10:

Compound 2:



[109] D'Amato (2001).

[110] December 20, 2011 Amendment and Response at p. 10 ('262 application file wrapper at p. 210).

222. *Fourth, falsity regarding the need to combine five references to get the claimed invention.* In the December 20, 2011 Remarks, Celgene asserted that combining the five references cited by the examiner (Kyle, Davies, Corral, Muller, and the '554) involved "impermissible hindsight," "elements of the claimed method are simply missing from even a combination of the five cited references," and "[t]he mere need to use five references to arrive at the claimed invention is an indication of its lack of obviousness."[111] Celgene continued: "The law requires a motivation to select the references and to combine them in the particular claimed manner to reach the claimed invention. *Eli Lilly & Co. v. Zenith Goldline Pharmaceuticals, Inc.,* at 1379 (Fed. Cir. 2006). The Examiner has provided no specific source of motivation to combine the teachings of the five references [Kyle, Davies, Corral, Muller, and the '554] for the claimed methods. Therefore, a *prima facie* case of obviousness has not been established."[112]

223. These statements, including the assertion that there was a "need to use five references to arrive at the claimed invention,"[113] were misleading and contained material omissions. Celgene and its agents knew that there would be no need to combine these five references, because *any one of* D'Amato (2001), Lentzsch (2001), Lentzsch (2002), Schey (June 2002), or Schey (October 2002)—or the patent that had already been granted to D'Amato—taught the crux of the claimed invention, i.e., pomalidomide for the treatment of multiple myeloma, rendering the claimed invention obvious, if not anticipated.

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[111] December 20, 2011 Amendment and Response at pp. 8-9 ('262 application file wrapper at pp. 208-209).

[112] December 20, 2011 Amendment and Response at p. 9. ('262 application file wrapper at p. 209).

[113] December 20, 2011 Amendment and Response at p. 9 ('262 application file wrapper at p. 209).

224. Because each of these references disclosed "a more complete combination of relevant features," the references were highly material. *See supra* at ¶ 55.

225. In short, Celgene's December 20, 2011, amendment and response was intended to deceive the examiner into withdrawing prior rejections, having the examiner not appreciate the full prior public disclosures regarding the potential to treat multiple myeloma using pomalidomide, and to believe the ostensible unexpected results were a lawful basis to allow the claims.

226. At this point in the patent prosecution (in late 2011/early 2012), Celgene, Zeldis, and Insogna had firmly led the examiner to believe Celgene and its scientists invented pomalidomide to treat multiple myeloma. At no point did Celgene or its agents disclose that the PTO *had already allowed* a patent to Dr. D'Amato claiming pomalidomide to treat multiple myeloma,[114] nor the lengths to which Celgene went to block that and other patents claiming pomalidomide to treat bloodborne tumors,[115] from issuing to D'Amato. Nor did Celgene disclose its systematic attempts to dismantle D'Amato's patent portfolio to clear the way for later-expiring patents claiming the same thing. Celgene hid all of this, while simultaneous attesting, "[the applicant] believes the named inventor or inventors to be the original and first inventor or inventors of the subject matter which is claimed and for which a patent is sought."[116]

227. Celgene's false and misleading statements and omissions were never remedied. Following Celgene's December 20, 2011 submission, the next interaction between Celgene and

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[114] Patent Application No. 10/166,539 (filed June 10, 2002, published October 31, 2002, and allowed December 13, 2002).

[115] Patent Application Nos. 09/899,344 (filed July 5, 2001, allowed Feb. 12, 2002, and re-allowed Oct. 21, 2002), 09/966,895 (filed Sept. 28, 2001), and 10/020,391 (filed Dec. 12, 2001, allowed April 16, 2002, and re-allowed Nov. 6, 2002).

[116] 37 CFR §1.63 (pre-AIA).

the examiner was an interview on March 1, 2012, during which "the Examiners and attorney for Applicant discussed allowability of the claims."[117] Having led the examiner to believe that Celgene scientists were the "original and first inventor[s]" of pomalidomide to treat multiple myeloma, the examiner was convinced to allow the patent. Had the truth been disclosed by Celgene, the examiner would not have approved its application. Instead, the focus of the patent prosecution after this point in time shifted to other aspects of the patent application, specifically, whether to narrow the patent claims to specific dosing regimens.

228. The examiner would not have concluded that Celgene was entitled to a patent claiming pomalidomide to treat multiple myeloma unless he did not know (because Celgene did not disclose) that a patent for the same claimed invention had already issued to someone else years earlier. On March 1, 2012, Celgene (along with Insogna's associate) initiated a call with the patent examiner (and another) to discuss the patent application. The examiner summarized the interview:

> "Discussed potential allowability of claims if independent claims are amended to incorporate the limitations of claim 1 of U.S. Pat 7,968,569. Particularly the cyclical administration of the current amounts of the compound for 21 consecutive days followed by 7 consecutive days of rest from administration of the compound in a 28 day cycle in combination with 40 mg of dexamethasone."[118]

229. The crux of the claimed invention (pomalidomide to treat multiple myeloma) was not novel, nor was the concept of cyclical administration of pomalidomide in combination with dexamethasone. For example, Kyle (2001) discloses methods of treating multiple myeloma by cyclically administering thalidomide and dexamethasone. Coleman (2002) taught the specific

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[117] March 15, 2012 Response and Statement of Interview Summary at p. 6. ('262 application file wrapper at p. 245).

[118] Typographical errors and misspellings corrected.

amount of 40 mg of dexamethasone combined with thalidomide to treat multiple myeloma. And Cohen (1982) taught the specific 28-day dosing regimen, *i.e.,* 21 days administration of an anticancer drug followed by 7 days of rest, in combination with dexamethasone. In treating cancer, it has long been a routine practice to administer the drug for a set period of time followed by a rest period. As the National Cancer Institute explains: "Some targeted therapies are given in cycles. A cycle is a period of treatment followed by a period of rest. The rest period gives your body a chance to recover and build new healthy cells."[119] The cyclical treatment of cancer is well known; and there is nothing novel about a week-based cycle (*i.e.* 21 days of treatment followed by 7 days of rest), which one would expect because it is predictable and easy to adhere to.

230. On March 15, 2012, Celgene (along with co-conspirators Insogna and Zeldis) submitted a response and statement of interview summary. The response amended the claims as contemplated at the March 1, 2012, meeting and reiterated that the examiner should withdraw all obviousness objections based on the representations it had made in its December 20, 2011, response.

231. On April 9, 2012, the patent examiner issued a notice of allowance of the '262 application. Celgene had obtained the '262 patent by fraud.

232. The examiner would not have allowed the '262 patent to issue absent the fraud committed by Celgene, Insogna and Zeldis.

233. In addition to the above fraud, the '262 patent is also manifestly invalid as obvious over the prior art. To highlight just a few references: the '539 patent application

[119] *Targeted Therapy to Treat Cancer*, National Cancer Institute https://www.cancer.gov/about-cancer/treatment/types/targeted-therapies (last updated May 31, 2022).

(published in October 2002 and allowed in December 2002) claimed pomalidomide to treat multiple myeloma; D'Amato (2001), Lentzsch (2001), Lentzsch (2002), Schey (June 2002), and Schey (October 2002) each taught pomalidomide to treat multiple myeloma and/or relapsed/refractory multiple myeloma; Celgene's own patent, the '517, claimed a method of using pomalidomide to reduce TFNα and taught reduction of TNFα as a cancer treatment; Davies (2001) taught IMiDs, which necessarily included pomalidomide, to treat multiple myeloma and relapsed/refractory disease; Kyle (2001) taught treatment of multiple myeloma by administering thalidomide in combination with dexamethasone;[120] Hideshima (2000) taught thalidomide and its analogues' ability to overcome drug resistance of multiple myeloma cells; Coleman (2002) taught 40 mg of dexamethasone combined with thalidomide to treat multiple myeloma; and Cohen (1982) taught the 21-day administration of an anticancer drug, followed by 7 days of rest, in combination with dexamethasone. The '262 did not claim anything beyond what was already known in the prior art.

234. In short, the '262 (and Celgene's other Pomalyst method of treatment patents) were invalid from their inception, as well as unenforceable due to Celgene's fraud on the patent examiner.

2. Shortly after the patent examiner allowed the '262, Celgene submitted its new drug application for Pomalyst.

235. On April 10, 2012, Celgene submitted a new drug application (NDA) to the FDA for approval to market Pomalyst (pomalidomide) capsules.

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[120] Kyle, Robert A., and S. Vincent Rajkumar. *Therapeutic Application of Thalidomide in Multiple Myeloma*. Seminars in Oncology 28, no. 6 583–87 (Dec. 1, 2001) doi:10.1016/S0093- 7754(01)90028- 4, summary available at https://journals.scholarsportal.info/details/00937754/v28i0006/583_taotimm.xml (last accessed Sept.4, 2023).

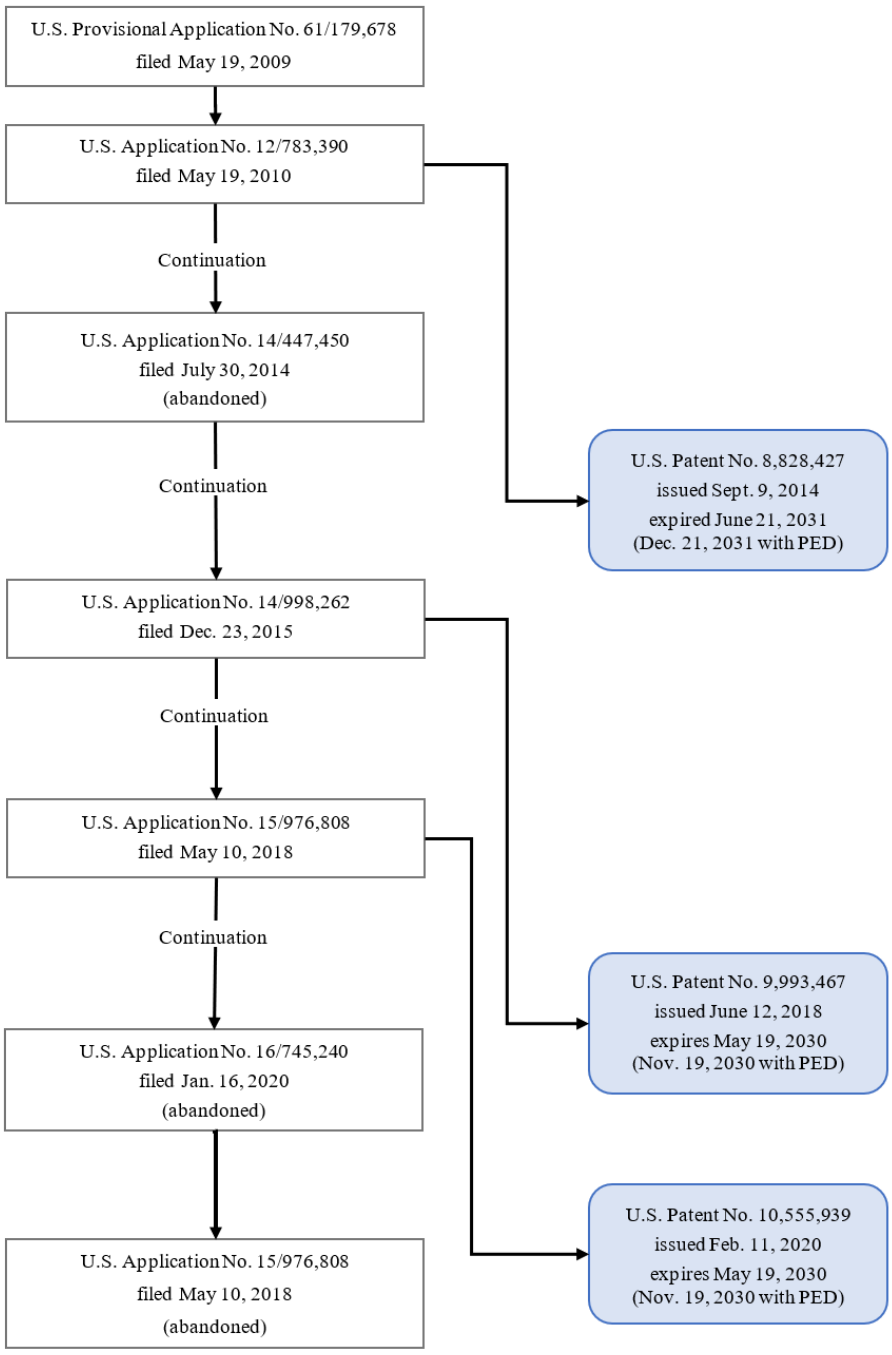
236. On February 8, 2013, the FDA approved Celgene's NDA for pomalidomide 1 mg, 2 mg, 3 mg and 4 mg capsules, under the brand name Pomalyst, in the treatment of patients with multiple myeloma who had received prior lenalidomide therapies and demonstrated disease progression. The recommended dosage was 4 mg daily on days 1-21 of a repeated 28-day cycle which could be taken with dexamethasone.

237. Following FDA approval, Celgene was granted a period of regulatory exclusivity. For new chemical entities, such as Pomalyst, the brand is granted a five-year exclusivity period. (This would provide a period for NCE exclusivity to February 8, 2018. Celgene would later tack onto this, by reason of its ill-gotten Pomalyst patents, further periods of exclusivity).

F. In 2009, Celgene also began seeking a series of formulation patents for Pomalyst by falsely claiming "unexpected results."

238. Beginning in 2009 (and continuing for over a decade), Celgene also sought a series of formulation patents for pomalidomide, falsely claiming its formulation showed "unexpected results" that were "surprising." Below is the Pomalyst formulation patent family:

POMALYST FORMULATION PATENT TREE



1. The prior art had already disclosed pomalidomide formulations as well as the need to address pomalidomide's instability issues.

239. Prior to Celgene's formulation patent applications, it was well known and well documented in the scientific community that thalidomide compounds are notoriously unstable

due to hydrolysis (*i.e.,* degradation of the compound in the presence of water).[121] These well-known stability issues have been addressed through routine optimization since well before the May 19, 2010 priority date for the '427 formulation patent.

240. There are also numerous sources, including Remington's Pharmaceutical Sciences, a pharmaceutical textbook first published more than 100 years ago, that teach methods of preparing oral dosage forms of various pharmaceutical compositions. As relevant here, the 17th edition of Remington's (published in 1985) teaches: the range of capsule sizes that can be swallowed and the capacity of each capsule size to hold a specified amount of powdered drug material; the use of excipients, such as mannitol; the advantages of spray drying mannitol; and the amount of filler or binder typically used.[122] In addition, sodium stearyl fumarate has been known since at least the 1990s to be an acceptable lubricant for capsules.[123] Additionally, Schey (June 2002) taught pomalidomide at specific dosing amounts, up to a maximum tolerated dosing amount of 5mg per day. In light of these references, it would have been well known in the scientific community how to make Pomalyst capsules in the claimed dosages well before the May 19, 2010 priority date for the '427 formulation patent.

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[121] *See e.g.* H. Schumacher, R. L. Smith, and R.T. Williams, *The Metabolism of Thalidomide: The Spontaneous Hydrolysis of Thalidomide in Solutions,* Brit. J. Pharmacol. (1965), 25, 324─337 ("in this paper we shall describe the conditions for the spontaneous hydrolysis of thalidomide in aqueous solution at various *p*H values.") available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1510736/pdf/bripharmchem00017-0044.pdf (last accessed June 20, 2025).

[122] The specific edition cited by the PTO is the 17th edition of Remington's Pharmaceutical Sciences (published in 1985) ("Remington's").

[123] *See e.g.,* the 5,593,696 patent ("McNally").

2. Celgene and its agents nonetheless pursued a Pomalyst formulation patent, which the examiner repeatedly rejected as obvious over the prior art.

241. On December 21, 2006, Celgene filed patent application no. 11/645,319 claiming pomalidomide in combination with an acceptable carrier or excipient. Zeldis was the first named inventor on the '319 application, and Insogna filed the application on behalf of Celgene. The '319 patent application disclosed that pregelatinized starch and mannitol are acceptable excipients for use in combination with pomalidomide. The '319 patent application was rejected four times, including for obviousness and double patenting. It was subsequently abandoned.

242. On May 19, 2009, Celgene filed provisional patent application no. 61/179,678. Insogna filed the '678 provisional application on behalf of Celgene. All the formulation patents at issue (the 8,828,427, 9,993,467, and 10,555,939) are related to this provisional patent application and therefore have a priority date of May 19, 2009. By this date, the '319 patent application, Remington textbook, and McNally's '696 patent, had all been disclosed in the prior art, and it was well known that thalidomide and its analogs faced stability issues due to hydrolysis.

243. On May 19, 2010, Celgene's Senior Director of Pharmaceutical Technology and Development, Anthony Tutino, filed patent application no. 12/783,390, which would lead to the '427 patent, the first of the Pomalyst formulation patents here at issue. Insogna prosecuted the '390 application on behalf of Celgene and its agent Tutino. The proposed patent claimed an oral dosage form of a given weight (*e.g.*, weighing "about 62.5 mg") comprised of pomalidomide and a pharmaceutically acceptable carrier or excipient, such as mannitol, pregelatinized starch, and sodium stearyl fumarate.

244. On April 24, 2012, the examiner rejected the patent application as obvious in light of the prior art, stating: "It would have been *prima facie* obvious to a person of ordinary skill

in the art at the time of the invention to have made oral dosage forms comprising pomalidomide and excipients such as mannitol and pre-gelatinized starch, with a reasonable expectation of success because Zeldis et al. taught such oral dosage forms." The examiner also pointed to Remington's as teaching capsule sizes and the benefits of spray drying common diluents like mannitol and to McNally as showing sodium stearyl fumarate is a known lubricant in the art.

245. The examiner also noted that, as defined and used in the patent application, since Celgene used the term "about" to describe the claimed amounts of pomalidomide and excipients, the amounts would be ranges: "The claims contain the term 'about' in front of quantities of active agents and excipients. Based on the specification the term 'about' is defined as a dose, amount, or weight percent within 30%, 25%, 20%, 15%, 10%, or 5% of the specified dose, amount, or weight percent. . . . Therefore, the claimed amounts of active and excipients are viewed as ranges." In other words, Celgene sought to define the scope of the claims very broadly.

246. On August 16, 2012, Celgene's counsel Insogna submitted an amendment and response arguing, "although Zeldis may generally disclose a laundry list of compostions [sic] containing pomalidomide in combination with a broad range of possible excipients that may be used in such compositions, there is no disclosure in Zeldis that would have prompted one skilled in the art to prepare a composition having pomalidomide at the specified amounts, along with the particular binders and fillers" as claimed.[124] Celgene and Insogna's assertion that "there is no disclosure in Zeldis that would have prompted one skilled in the art to prepare a composition having pomalidomide at the specified amounts"[125] was misleading, because Celgene and Insogna

[124] Aug. 16, 2012 Amendment and Response at p. 9 ('427 application file wrapper at p. 173).

[125] *Id.*

failed to disclose that Schey (June 2002) taught pomalidomide dosage amounts up to a maximum tolerated dosage of 5 mg per day. Celgene and Insogna dismissed Remington and McNally as prior art on the basis that they did not teach the advantages of the specific oral dosage forms claimed.

247. On November 15, 2012, (and despite Celgene's misrepresentations and omissions), the examiner again rejected the patent application on the basis that the claimed invention was obvious over Zeldis in view of Remington's and McNally's. The patent examiner also rejected the claims for failure to comply with the written description requirement, stating that Celgene failed to "convey to one skilled in the relevant art that the inventor . . . at the time the application was filed, had possession of the claimed invention," and for indefiniteness.

248. The examiner was also not initially persuaded by Celgene's claims regarding "unexpected results" in part because the submission "lack[ed] data that shows alleged unexpected results." The patent examiner continued, "[i]n the instant case the applicant did not show that the results were unexpected, unobvious, and of both statistical and practical significance. Applicant instead provided a conclusion that advantageous and unexpected properties were observed without showing any evidence that supports those conclusions . . . this is not sufficient to overcome obviousness."

3. In 2013, Celgene and its agents submitted the fraudulent Tutino Declaration claiming "unexpected results" to overcome the patent office's rejections and to obtain fraudulently the '427 formulation patent

249. On June 17, 2013, to overcome the examiner's repeated rejections of the '427 patent application, Celgene, along with Insogna, submitted a sworn declaration by Tutino (Tutino Declaration) with data ostensibly supporting Celgene's assertion of patentability based

on "unexpected results."[126] The Tutino Declaration does not specify when the reported testing was conducted, vaguely stating that "tests have been conducted between pomalidomide and various candidate excipients." Other concerns exist about the data Tutino selected for inclusion, but regardless, the fundamental issue is that Tutino mischaracterizes the data to deceive the examiner into believing something that is not true, i.e., that the data showing instability would have been unexpected over what was known in the prior art. Tutino's assertion is unfounded. Thalidomide is notoriously unstable due to hydrolysis (*i.e.,* degradation of the compound in the presence of water), a fact that has been well known and well documented in the scientific community for decades. Tutino feigns ignorance of these known stability issues and, when he encounters hydrolysis (which he addresses through standard, routine optimization), proclaims this was "unexpected." There would have been nothing surprising or "unexpected" about these stability issues given the known tendency of thalidomide compounds to degrade in the presence of water. And it would have been routine practice to address these known stability issues as part of the formulation process. Celgene, Insogna, and Tutino deceived the patent examiner when they told the examiner otherwise.

250. As the generic manufacturers explained in the patent litigation:

> Celgene also relied on selected data to show that certain other formulations present a compatibility problem, ***i.e.***, were unstable after two weeks storage. Declaration of Anthony Tutino, June 14, 2014 at ¶ 8. Celgene then presented long-term stability data to show that only one of the formulations was shown to be stable beyond 3 months. ***Id.*** at ¶ 9-10. However, any purported superior property must be unexpected to be considered as evidence of non-obviousness, and **routine optimization within the ordinary skill of a POSA fails to meet this standard**. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1368, 82 U.S.P.Q.2d 1321, 1336 (Fed. Cir. 2007) (routine optimization to reach adequate physicochemical characteristics, including stability, is not evidence of unexpected results). **There is nothing in Mr. Tutino's declaration to suggest that the steps taken to optimize the formulation**

[126] *See* MPEP (8th ed. Rev. 7, July 2008) at § 2145.

> **were anything less than routine, or that he did not expect to reach a stable formulation. Thus, Celgene has not shown evidence of any unexpected results** tied to the claimed combination of excipients present in the claimed amounts.
>
> A person having ordinary skill in the art would be able to vary the amounts of each of the claimed excipients, which were well-known, within known ranges to optimize the properties of the formulation and arrive at a stable formulation. Indeed, a stable formulation must have been created previously as used in Schey III, which administered capsules containing pomalidomide to multiple myeloma patients in the range of 1 to 10 mg per day. See also Marriott 2002, Schey I, Schey II, & Section II.C.2.[127]

251. Following Celgene and its agents' submission of the misleading Tutino Declaration, the examiner allowed the '427 formulation patent to issue.

252. In the "Reasons for Allowance" section of the "Notice of Allowance," the examiner explained that:

> Applicant submitted a declaration on 06/17/2013 by declarant Anthony Tutino, where the declarant stated that one of ordinary skill in the art could not have predicted compatibility of pamolidomide [sic] with the excipients in the inventive composition based on the teachings of Zeldis. . . . After taking into consideration the breadth of the claims and the declaration, the claimed compositions were not obvious over the prior art of record because one of ordinary skill in the art could not have selected the specific oral dosage formulations as claimed from Zeldis reference with a reasonable expectation in obtaining formulations that are stable under tested conditions because **applicant showed in a declaration that stability of pomalidomide in formulation comprising various excipients is not predictable. The prior art of record is silent with respect to stability of pomalidomide when combined with various excipients**.[128]

253. The Tutino Declaration was material information on which the patent examiner justifiably relied. The '427 would not have issued but for the false representations and deliberate omissions in the declaration regarding the prior art and the purportedly unexpected results.

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[127] *Celgene v. Hetero, et al.,* No. 17-cv-3387 (D.N.J.), Defendants' Invalidity Contentions with Respect to Patent Nos. 8,198,262; 8,673,939; 8,735,428 and 8,828,427 at pp. 187-188 (ECF No. 922, Exhibit D.

[128] Notice of Allowability at p. 3 ('427 patent file wrapper at p. 370) (emphasis added).

254. Because the Tutino Declaration concerned an expert opinion regarding what would have been unexpected in light of prior research, the examiner was necessarily constrained to give that assertion, even if couched as an "opinion," "considerable deference."[129] The examiner had repeatedly rejected the patent as obvious. But following the submission of the Tutino Declaration, the examiner allowed the patent, indicating the examiner relied on the false and misleading Tutino Declaration and that the patent would not have been issued absent that declaration.

255. Although the examiner allowed the '427 patent to issue, it allowed only a narrow set of claims (claims that were easy to design around to avoid infringement). The approved claims are to a capsule comprising pomalidomide, pregelatinized starch, sodium stearyl fumarate, and spray-dried mannitol, where the capsule is one of six specific weights, *i.e.,* "[a]n oral dosage form in the form of a capsule which weighs [x] mg. . . ." where "[x]" is either 62.5, 125, 250, 180, 240, or 300 mg. A generic manufacturer would readily be able to design around this patent by, *inter alia*, developing a capsule with a weight other than one of the six weights claimed by the patent.

256. The '427 was invalid due to Celgene's fraud on the patent office, and additionally it was so narrow that a generic manufacturer could easily design around it. Therefore, the '427 should not have been a barrier to generic entry.

G. In 2013-2014, Celgene defrauds the patent office to obtain two more method of treatment patents (the '428 and '3939).

257. On March 1, 2013, Celgene filed two patent applications seeking to extend or broaden method of use patent protection for pomalidomide. The applications (nos. 13/782,612

[129] MPEP (8th ed. Rev. 7, July 2008) at § 716.01(c).

and 13/782,728) continued in the '262 family and claimed priority back to the November 2002 provisional application. Zeldis is the first named inventor on both applications, which would lead to the 8,735,428 and the 8,673,939 method of treatment patents, respectively.

258. Patent application no. 13/782,612 (leading to the '428) claimed *inter alia* a method of treating multiple myeloma with pomalidomide for 21 days followed by 7 consecutive days of rest, where the multiple myeloma is relapsed and/or refractory and there is demonstrated disease progression after certain specified treatments. Although the proposed claims included a dependent claim for the administration of pomalidomide in combination with dexamethasone, the independent claim did not specify treatment in combination with dexamethasone.

259. The independent claims of the '3939 patent are the same as the '428, except the '3939 states that the compound is to be administered in "one or more cycles, each of which comprises administering the compound for a period of time followed by a period of rest," rather than specifying the exact cyclical schedule (*i.e.,* 21 days followed by 7 consecutive days of rest). The two patents were prosecuted in parallel, with essentially the same submissions, meetings, and evidence; the following discussion summarizes the prosecution history for the '428, which is substantially similar for the '3939.

260. The previously-issued '262 includes two independent claims for using pomalidomide to treat multiple myeloma and several dependent claims claiming treatment of relapsed and/or refractory multiple myeloma:

Independent (Claim 1)	A method of treating multiple myeloma, which comprises administering to a patient having multiple myeloma: (a) from about 1 mg to about 5 mg per day of a compound having the formula: [pomalidomide compound structure] or a pharmaceutically acceptable salt, Solvate or stereoisomer thereof for 21 consecutive days followed by seven consecutive days of rest from administration of said compound in a 28 day cycle, and (b) 40 mg of dexamethasone.

Dependent claim (Claim 2)	The method of claim 1, wherein the multiple myeloma is relapsed and refractory multiple myeloma.
Dependent claim (Claim 4)	The method of claim 1, wherein the multiple myeloma is refractory multiple myeloma.
Dependent claim (Claim 5)	The method of claim 1, wherein the multiple myeloma is relapsed multiple myeloma.
Dependent claim (Claim 6)	The method of claim 1, wherein the patient has received previous therapy.
Dependent claim (Claim 7)	The method of claim 1, wherein the patient has demonstrated disease progression on previous therapy.
Dependent claim (Claim 8)	The method of claim 1, wherein the patient has received previous therapy and has demonstrated disease progression on previous therapy.
Independent claim (Claim 20)	A method of treating multiple myeloma, which comprises administering to a patient having multiple myeloma: (a) from about 1 mg to about 5 mg per day of a compound having the formula: [pomalidomide compound structure] for 21 consecutive days followed by seven consecutive days of rest from administration of said compound in a 28 day cycle, and (b) 40 mg of dexamethasone on at least one of days 1-21 of said cycle.
Dependent claim (Claim 29)	The method of claim 20, where the multiple myeloma is relapsed and refractory multiple myeloma.

261. The ’428 and ’3939 patents incorporated the treatment of relapsed and/or refractory multiple myeloma into the independent claims in those patents:

’428	’3939
1. A method of treating multiple myeloma, which comprises administering to a patient	**1.** A method of treating multiple myeloma, which comprises administering to a patient

having multiple myeloma, and which patient has previously received therapy for multiple myeloma, from about 1 mg to about 5 mg per day of a compound having the formula: [pomalidomide compound structure] or a pharmaceutically acceptable salt, solvate or stereoisomer thereof for 21 consecutive days followed by seven consecutive days of rest in a 28 day cycle, wherein the multiple myeloma is relapsed, refractory, or relapsed and refractory.	having multiple myeloma, and which patient has previously received therapy for multiple myeloma, from about 1 mg to about 5 mg per day of a compound having the formula: [pomalidomide compound structure] or a pharmaceutically acceptable salt, solvate or stereoisomer thereof, wherein the compound is administered in one or more cycles, each of which comprises administering the compound for a period of time followed by rest, wherein the multiple myeloma is relapsed, refractory, or relapsed and refractory.
22. A method of treating multiple myeloma, which comprises administering to a patient having multiple myeloma, and which patient has received previous therapy for multiple myeloma and has demonstrated disease progression on the previous therapy, from about 1 mg to about 5 mg per day of a compound having the formula: [pomalidomide compound structure] or a solvate thereof, for 21 consecutive days followed by seven consecutive days of rest in a 28 day cycle.	**26.** A method of treating multiple myeloma, which comprises administering to a patient having multiple myeloma, and which patient has received previous therapy for multiple myeloma and has demonstrated disease progression on the previous therapy, from about 1 mg to about 5 mg per day of a compound having the formula: [pomalidomide compound structure] or a solvate thereof, wherein the compound is administered in one or more cycles, each of which comprises administering the compound for a period of time followed by a period of rest.

262. On June 11, 2013, the examiner conducted an interview with Celgene regarding the method of treatment patent application.

263. On July 9, 2013, the examiner rejected the claims on the basis of double patenting over the '262.[130] The patent examiner also rejected the claims because "the claimed invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made." The prior art references cited by the examiner included Kyle

[130] The '262 patent is erroneously referred to here as 8,198,232. The error is subsequently noted and corrected.

(2001), Davies (2001), Corral (1999), Muller (1999), and the '554. Regarding the claims "wherein the previous therapy is, *inter alia,* thalidomide, lenalidomide or a proteasome inhibitor," the examiner stated in part, "one of ordinary skill in the art would have understood that [pomalidomide] would provide benefits in treating [multiple myeloma ("MM")] whether the patient had previous therapy with thalidomide, lenalidomide, proteasome inhibitor, etc. The skilled artisan would have at least found it obvious to try in these patients as well as others with MM."

264. On October 4, 2013, the patent examiner conducted an interview with Celgene representatives, including Celgene's attorney Ms. Moon; Dr. Anjan Thakurta, Senior Director in Translational Development at Celgene; Robertson-Chow for "Celgene Corporation, Assignee of the present application"; and Wei Zhang, the attorney for the patent applicant, Zeldis. According to the interview summary,[131] in order to overcome the examiner's rejection of the patent, the "Applicant submitted that the claims, as is, are patentable because pomalidomide (POM) alone was shown to unexpectedly treat multiple myeloma that is or has become resistant to lenalidomide (LEN). . . . Applicant submitted that one of ordinary skill in the art would not have recognized this because, inter alia, the compounds are so close in structure."

265. This assertion by Celgene and its agents during the October 4, 2013 interview—that it was unexpected that Pomalyst can be used to treat multiple myeloma that has become resistant to Revlimid (lenalidomide)—was false. Although the examiner had previously rejected the patent application, after Celgene and its agents made the false interview statements, the examiners were led to believe that Celgene had demonstrated unexpected results supporting a claim of patentability: "The Examiners agreed that Applicant has shown unexpected results and

[131] The interview summary is dated October 13, 2013.

suggested the Applicant present arguments and any supporting data in the form of a declaration."[132]

266. On October 8 and 9, 2013, to address the examiner's double patenting objection, Celgene filed the following terminal disclaimers:

Patent application	Resulting patent	Terminal disclaimer as to:
13/782,612	'428	(a) the '262
13/782,728	'3939	(a) the '262 and (b) any patent resulting from patent application no. 13/782,612

267. On October 9, 2013, to address the examiner's request for a sworn statement of Celgene's assertions made during the examiner interview, Celgene submitted the declaration of Thakurta (the "Thakurta Declaration") along with its Amendment and Request for Reconsideration. Thakurta is not a clinician and, at the time he produced this opinion, had no experience working on clinical trials. Nor was Thakurta a registered physician involved in treating patients. Thakurta does not appear to be a person qualified to offer an opinion (a "person of ordinary skill in the art" or "POSA") on the matters set forth in his declaration.

268. Setting aside whether Dr. Thakurta was or was not a qualified POSA, he is a scientist with a PhD who Celgene held out as an expert possessing facts that would aid the examiner in assessing whether the claimed invention was obvious in light of the prior art. To overcome the examiner's rejection for obviousness, Celgene and its agents submitted the Thakurta Declaration falsely asserting "unexpected results," that is, that it was not known that pomalidomide could be used to treat multiple myeloma that had become resistant to lenalidomide: "It has been surprisingly found that the resistance of multiple myeloma cells to

[132] Applicant-Initiated Interview Summary from Oct. 4, 2013 Interview at p. 1 ('428 application file wrapper at p. 226).

pomalidomide and lenalidomide is not reciprocal. . . . It is therefore my opinion that the results of the studies for treating relapsed and/or refractory multiple myeloma with single-agent pomalidomide would have been unexpected and surprising at the time the claimed invention was made."[133] Thakurta further attested that "pomalidomide is able to exert its activities with a lesser amount of the target . . . This mechanism of action and the unique benefit of pomalidomide are not obvious or predictable from the disclosure of the references cited in the Office Action."

269. Thakurta's statements were false. At the time of the claimed invention, the use of thalidomide analogues for the treatment of relapsed/refractory disease and the ability of thalidomide analogues, including pomalidomide, to overcome drug resistance of multiple myeloma cells was well known in the prior art.

270. It was also known that pomalidomide was many times more potent than other thalidomide analogs, including lenalidomide. Celgene had already, as part of the 1998-1999 reexamination of the '517, touted the ostensible 10,000-fold increase in activity represented by pomalidomide (which in fact was 3-4 times). It was well known that, once a patient's myeloma had become resistant to one thalidomide analog (e.g., lenalidomide), the patient would be moved to a more potent thalidomide analog (e.g., pomalidomide). It would also be evident to one of ordinary skill in the art that, if a patient's myeloma became resistant to the analog with greater potency, a less potent analog would not be effective (i.e., the nonreciprocal nature of the two drugs was well known). Thakurta's sworn declaration asserting that it was unknown that the more potent drug, pomalidomide, would work in patients who had become resistant to the less potent drug, lenalidomide, was false. It was also false to assert that it would be unknown that a

[133] October 7, 2013 Declaration by Anjan Thakurta, Ph.D. under 37 C.F.R. 1.132 at p. 3 ('428 application file wrapper at p. 205).

more potent drug would require a smaller dose (see statements by Thakurta quoted above claiming that it was not obvious that pomalidomide would be "able to exert its activities with a lesser amount of the target").

271. Thakurta made these deceptive representations and omissions with the intent to deceive the patent examiner. Thakurta discussed specific studies in the field and offered an expert opinion on what the prior art taught. A sworn expert declaration of this nature, seemingly based on factual evidence, would be given consideration and weight by a reasonable patent examiner.[134] The examiner justifiably relied on the information provided by Thakurta, as evidenced by the examiner's reversal of its prior decisions rejecting the patents, allowing the patents to issue after Thakurta submitted his declaration. Because the examiner had rejected the patent, and only allowed it to issue after Celgene submitted the false Thakurta Declaration, it is clear that the patent would not have issued but for the false Thakurta Declaration.

272. On October 9, 2013, concurrently with the submission of the Thakurta Declaration, Celgene and its agents submitted Remarks responding to the examiner's prior rejection of the patent application for the '428 patent. In the October 9 Remarks, Celgene and its agents reiterated that "one skilled in the art would not have expected that pomalidomide would be able to treat multiple myeloma that is relapsed after or refractory to prior treatment."[135] This statement was false and misleading and omitted material information for the reasons stated above.

273. In its October 9 Remarks, Celgene and its agents made additional false and misleading statements and material omissions including:

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[134] MPEP (8th ed. Rev. 7, July 2008) at § 716.01(c).

[135] Oct. 9, 2013 Response at p. 6 ('428 application file wrapper at p. 195).

Statement: "Kyle does not disclose or suggest the doses recited in the instant claims (about 1 to about 5 mg/day). . . . The doses used in Kyle are much higher than those recited in the instant claims. Thus, even if Kyle motivated one to select pomalidomide, and it does not, Kyle teaches away from the claimed dosage range."[136]

Falsity: Celgene asserted that Kyle did not disclose the dosage range for pomalidomide, while omitting to disclose that Schey (June 2002) did disclose the dosing range for pomalidomide (up to a maximum of 5mg/day). The examiner does not mention Schey (June 2002) at any point during the '428 patent prosecution.

Statement: "The Patent Office admits that Davies does not teach pomalidomide."[137]

Falsity: Davies (2001) taught that pomalidomide can act directly on multiple myeloma cells and is useful in relapsed/refractory disease. In its Remarks, Celgene and its agents claimed that Celgene used the terms in the article (IMiD1, IMiD2, IMiD3) "to designate different compounds at different times in different publications," while failing to disclose that the article in fact referred to pomalidomide and falsely asserting that "Davies does not teach pomalidomide."

Statement: "Davies does not teach or suggest that pomalidomide is more effective that thalidomide in the treatment of multiple myeloma. There would be no basis in Davies to select one compound over the other."[138]

Falsity: Davies (2001) disclosed that the new thalidomide analogs are 50,000 times more potent in inhibiting TNFα as compared to thalidomide.

Statement: "[T]he Patent Office has provided no specific source of motivation to combine the teachings of the four references in the particular claimed manner. . . . Even if the cited references were combined as the Patent Office alleges, the combination would not have provided the requisite expectation of success."[139]

Falsity: Celgene omits that one would not need to combine four references to arrive at the claimed invention, because other prior art references contained a more complete disclosure of the claim elements, any one of which teaches the crux of the claimed invention.[140]

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[136] Oct. 9, 2013 Response at p. 8 ('428 application file wrapper at p. 197).

[137] Oct. 9, 2013 Response at p. 9 ('428 application file wrapper at p. 198).

[138] Oct. 9, 2013 Response at p. 10 ('428 patent file wrapper at p. 199).

[139] Oct. 9, 2013 Response at p. 10 ('428 patent file wrapper at p. 199).

[140] *See e.g.,* Schey (June 2002) (teaching pomalidomide to treat relapsed/refractory multiple myeloma); or Schey (October 2002) (same); or Davies (2001) (disclosing that thalidomide and immunomodulatory drugs, including pomalidomide, can be used to treat multiple myeloma and are useful in relapsed/refractory disease).

> **Statement**: "A skilled artisan would have no reason to use the specific claimed dose (about 1 to about 5 mg/d) of the instant compound (pomalidomide) from the cited art."[141]
>
> **Falsity**: Celgene omits to disclose that Schey (June 2002) disclosed the dosing range for pomalidomide (up to a maximum of 5mg/day). The examiner does not mention Schey (June 2002) at any point during the '428 patent prosecution.

274. The additional false and misleading statements and material omissions described in the preceding paragraph are part of Celgene and its agents' pattern of intentionally making false and misleading statements to the PTO in the pursuit of method of treatment patents claiming uses for pomalidomide.

275. But it was Celgene's and Thakurta's false statements and material omissions regarding unexpected results that was the deciding factor in the PTO's decision to reverse the prior rejection and allow the '428 method of treatment patent. As explained in the October 4, 2013 interview summary:

> Applicant submitted that any alleged prima facie case of obviousness would be overcome by a showing of unexpected results. Applicant submitted that the claims, as is, are patentable because pomalidomide (POM) alone was shown to unexpectedly treat multiple myeloma that is or has become resistant to lenalidomide (LEN), a structurally close analog of POM that is known to be effective for treating multiple myeloma. Applicant submitted that one of ordinary skill in the art would not have recognized this because, inter alia, the compounds are so close in structure. The Examiners agreed that Applicant has shown unexpected results and suggested Applicant present the arguments and any supporting data in the form of a declaration.[142]

276. Celgene and its agents (including named inventor, prominent clinical researcher, and senior executive at Celgene, Zeldis, and Celgene scientist and executive Thakurta) made these false and misleading statements and material omissions during the course of the '428

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[141] Oct. 9, 2013 Response at p. 11 ('428 application file wrapper at p. 200).

[142] Aplicant-Initiated Interview Summary from Oct. 4, 2013 Interview, at p. 1 ('428 application file wrapper at p. 226).

and '3939 patent prosecutions in violation of the duties of candor, good faith, and disclosure owed to the examiner.

277. On October 17, 2013 (as memorialized in a November 6, 2013 submission to the PTO), Celgene and its agents contacted the PTO to make a slight correction to the earlier interview summary, clarifying that Celgene and its agents had described lenalidomide and pomalidomide as "chemical analogs," not "structurally close analog[s]" or "so close in structure, to which the examiner responded that the summary is "not a verbatim record."

278. On January 15, 2014, a notice of allowance was mailed to Celgene for the '428 patent. Other than the minor correction to the interview summary described in the preceding paragraph, there were no other events in the patent prosecution between the October 9, 2013 false Remarks and false Thakurta Declaration and the January 15, 2014 notice of allowance.

279. Through the deception of its agents, including Zeldis and Thakurta, Celgene achieved its goal. On March 18, 2014, and May 27, 2014, respectively, the examiner issued the '3939 and '428 patents, further extending Celgene's unlawful Pomalyst monopoly. Absent its deceptive representations and deliberate omissions, neither the '428 nor the '3939 would have issued. Both patents are unenforceable due to the fraudulent conduct of Celgene and its agents, and invalid as obvious over the prior art.

H. In 2015, Celgene sought and later procured a second Pomalyst formulation patent (the '467) by fraud.

280. On December 23, 2015, Celgene filed patent application 14/998,262, which would lead to the '467 formulation patent. The named inventor on the patent application was Tutino.

281. As originally styled, the application sought to expand the scope of the previous formulation claims (which required formulations in absolute weight terms) by now claiming

formulations in terms of the relative weight of pomalidomide to the combined binders and fillers.

282. Over the next two and a half years, the patent examiner repeatedly, and correctly, rejected the claims in the application as obvious.

283. On February 7, 2017, the examiner rejected the claims for a third time, stating in part:

> Applicant's arguments directed to picking and choosing and impermissible hindsight are not persuasive because **Zeldis teaches a limited list of fillers** [] (talc, calcium carbonate, microcrystalline cellulose, cellulose, dextrates, kaolin, mannitol, silicic acid, sorbitol, starch, pregelatinzed starch, and mixtures thereof), **a limited list of disintegrants** [] (agar-agar, alginic acid, calcium carbonate, microcrystalline cellulose, croscarmellose sodium, crospovidone, polacrilin potassium, sodium starch glycolate, potato starch, tapioca starch, starches, pre-gelatinized starch, clays, algins, celluloses, gums, and mixtures thereof), and **a limited list of lubricants** []. It would have been obvious to have formed a solid dosage form comprising pamolidomide [sic] in any combination of filler(s), binder(s), and lubricant(s) as described by Zeldis. Zeldis teaches ranges of concentrations of the components and it would have been obvious to have varied the amounts of components within the taught ranges. A person of ordinary skill in the art would have arrived at the claimed invention through **routine experimentation** and it would have been **obvious** to have formed a solid dosage form from any possible combination of excipients disclosed by Zeldis.[143]

284. Meanwhile, would be generic makers had been developing their products. On February 8, 2017—the first date on which ANDA applicants could file an application for generic pomalidomide—at least seven generic manufacturers (Teva, Natco/Breckenridge, Apotex, Hetero, Par, Aurobindo, and Mylan) filed ANDAs to market generic Pomalyst.

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[143] Advisory Action Before the Filing of an Appeal Brief regarding Oct. 26, 2016 Reply at p. 2 ('467 application file wrapper at 427).

285. In the following months, some ANDA applicants provided information to Celgene about their ANDA products, including how some ANDA applicants had formulated their versions of generic pomalidomide.

286. By September of 2017, Celgene had a plan as to how to modify the pending formulation claims to increase the scope of the previously approved formulation claims (and thereby increase the potential for infringement by would-be competitors) while at the same time potentially persuade the examiner to issue a patent.

287. On September 21, 2017, an interview was conducted between the patent examiner and Celgene's representatives, during which Celgene represented that it could supply a declaration showing unexpected stability results.

288. On October 20, 2017, Celgene amended the claims to add a requirement that the starch to mannitol ratio be from 1:1 to 1:1.5. And on February 22, 2018, Celgene submitted yet another response and a new declaration by Tutino.

289. The February 2018 Tutino declaration was false and misleading. First, the declaration presents undated stability test results of six formulations of pomalidomide (0.5 mg, 1.0 mg, 2.0 mg, 3.0 mg, 4.0 mg and 5.0 mg) and falsely states the stability results are surprising and unexpected. It was well known and well documented in the prior art that thalidomide and its analogs such as pomalidomide posed stability issues, which a person skilled in the art would have been aware of in conducting the type of routine experimentation that led to the claimed invention. And the techniques to achieve stable formulations of such compounds were also well known. Second, the formulations presented used only two close ratios of starch to mannitol (i.e., 1:1.30402385 and 1:1.33069307) and did not support the range claimed by Celgene (i.e., 1:1.0 to 1:1.5).

290. On March 15, 2018, the examiner allowed the '467 formulation patent to issue, subject to a terminal disclaimer as to the '427 patent.

291. The '467 patent would not have issued absent the deceptive declarations submitted by Tutino during the patent prosecution. The second Tutino Declaration repeats the same fraudulent representations as the first Tutino Declaration regarding "unexpectedly" encountering and addressing stability issues, which Tutino supplements in his second declaration with undated testing data. There would have been nothing surprising about the well-known fact that thalidomide analogs are unstable due to hydrolysis, an issue that would be addressed through standard, routine optimization. Tutino misled and deceived the patent examiner when he suggested otherwise.

292. The examiner justifiably relied on the deceptive Tutino declarations, allowing the patents to issue based on the submission of the Tutino declarations after repeated prior rejections of the claims.

293. In addition to being unenforceable, the '467 is invalid for obviousness and, in any event, is very limited in scope. During the patent prosecution (during which Celgene saw its claims rejected four separate times), Celgene was forced to narrow the claims substantially. As issued, the '467 has one independent claim, which claims:

> An oral dosage form in the form of a capsule which comprises: 1) pomalidomide at an amount of 0.1 to 3 weight percent of the total weight of the composition; 2) a binder or filler at an amount of 90 to 99 weight percent of total weight of the composition, wherein the binder or filler is a mixture of starch and mannitol; and wherein the ratio of mannitol: starch in the dosage form is from about 1:1 to about 1:1.5 . . . ."

294. Thus, even if the patent was valid, it is highly unlikely Celgene would be able to prove infringement. The '467 does not claim any kind of complexity, such as bioequivalence metrics, that would require a generic manufacturer to do extensive testing to ascertain whether

its formulation would infringe. Instead, the patents are more akin to a recipe, identifying a finite list of ingredients (primarily pomalidomide, starch, mannitol, and sodium stearyl fumarate) combined in certain specified amounts or ratios. A generic manufacturer would be able to design around these patents to produce a non-infringing product, for example, by adjusting the ratios or by using different binders/fillers, while still maintaining the desirable features, such as stability and bioavailability.

I. In February 2017, numerous generic manufacturers filed generic Pomalyst ANDAs, leading to the first wave of patent infringement lawsuits by Celgene.

295. Because the FDA had first approved Pomalyst on February 8, 2013, under regulations governing new chemical entity exclusivities, the first date upon which a generic company could file an ANDA for generic Pomalyst was February 8, 2017 (four years after approval, if challenging patents). In such situations, it is not uncommon to see multiple generics all file on the first available date.

296. On February 8, 2017, at least seven generic manufacturers (Teva, Natco/Breckenridge, Apotex, Hetero, Par, Aurobindo, and Mylan) filed ANDAs to market generic Pomalyst.[144] These generics all sought first-to-file status, with the potential for the 180-day exclusivity so long as they obtained timely tentative or final drug approval.

297. At least nine ANDAs have been filed to date[145], listed here.

Generic	ANDA No.
Teva	209956
Natco/Breckenridge	210111
Apotex	210164

[144] The final approval letters for Natco/Breckenridge and Aurobindo state that the filing dates for these ANDA is February 8, 2017. The final approval letter for Mylan is not publicly available. Plaintiff has inferred that the Mylan ANDA, as well as the Teva, Apotex, Hetero, and Par ANDAs were also filed on February 8, 2017, based in part of the dates the paragraph IV letters were sent (as disclosed in Celgene's complaints against these entities).

[145] In 2018 and 2019, Synthon/Alvogen and DRL, respectively, filed ANDAs.

Generic	ANDA No.
Synthon/Alvogen	210232
Hetero	210236
Par	210245
Aurobindo/Eugia	210249
Mylan	210275
Dr. Reddy's	213234

298. In late March/early April 2017, Celgene received seven paragraph IV letters from the ANDA filers certifying that Celgene's Pomalyst patents were either invalid and/or would not be infringed by the manufacturer's ANDA product.

299. On May 4, 2017, Celgene filed its first Pomalyst patent infringement lawsuit. The suit, against Par and Teva, alleged infringement of four patents. On May 11, 2017, Celgene sued Hetero, Aurobindo/Eugia, Apotex, Mylan, and Natco/Breckenridge, for infringement of the same four patents:

8,198,262	Method of treatment
8,673,939	Method of treatment
8,735,428	Method of treatment
8,828,427	Formulation

300. All four of the asserted patents were unenforceable due to Celgene's fraud on the patent office, invalid as obvious over the prior art, and, in the case of at least the '427, subject to strong non-infringement arguments. However, by simply filing these patent lawsuits, Celgene triggered an automatic 30-month stay, which was extended to August 8, 2020 (*i.e.,* 7.5 years after NDA approval) due to the NCE exclusivity. During this time, the FDA was barred from granting final approval to any ANDA.

1. Celgene's lawsuits alleging infringement of the Pomalyst method of treatment patents (the '262, '428, '3939) and the only then-existing formulation patent (the '427) were a sham.

301. Celgene's infringement lawsuit was objectively and subjectively baseless. A reasonable pharmaceutical company in Celgene's position could not realistically expect to succeed on the merits of its lawsuits alleging infringement of the method of treatment patents and the '427 formulation patent. Celgene pursued lawsuits against generics not because it had any realistic expectation of success on the merits, but rather as a way to use the litigation process as an anticompetitive weapon to delay generics from entering the pomalidomide market and to extend Celgene's monopoly.

302. All four patents were obtained through fraud on the patent examiner and were therefore unenforceable. Celgene defrauded the PTO when applying for its method of treatment patents by, among other things, failing to disclose that D'Amato had obtained a patent claiming pomalidomide to treat multiple myeloma years before Celgene filed its own method of treatment patents and (for the subsequent method of treatment patents) and; submitting the false Thakurta Declarations claiming unexpected results. *See* Section G, *supra.* Celgene similarly obtained the '427 patent through fraud by, *inter alia,* submitting the false Tutino Declaration claiming unexpected results. *See* Sections F, *supra.* Because Celgene's fraudulent and deceptive conduct would have been revealed during the patent litigation, Celgene could not have expected that it would prevail in the patent infringement litigation.

303. Irrespective of the fraud on the patent examiner, Celgene's litigation against the generic manufacturers for infringement of the '262, '428, '3939, and '427 was a sham for the independent reason that there was no legitimate or objective basis to assert that the method of treatment patents or the formulation patent were valid and infringed.

304. First, with respect to the method of treatment patents, a reasonable litigant in Celgene's position would not have expected to prevail on arguments that the patents were nonobvious, given the extensive prior art teaching the claimed invention. That prior art included the patent already allowed to D'Amato claiming pomalidomide to treat multiple myeloma (the '539 patent application), and other references, including D'Amato (2001), Lentzsch (2001), Lentzsch (2002), Schey (June 2002), and Schey (Oct. 2002), each of which taught the crux of the claimed invention. Unlike the *ex parte* proceedings that led to the issuance of Celgene's method of treatment patents, Celgene's patent litigation against the generics were adversarial proceedings involving sophisticated pharmaceutical companies incentivized to prove Celgene's patents were invalid.

305. Given the overwhelming evidence of obviousness, no reasonable pharmaceutical company in Celgene's position could have realistically expected to prevail on a claim that the method of treatment patents were valid and infringed. Second, regarding the '427 formulation patent, no reasonable litigant in Celgene's position could have expected to prove nonobviousness—and thus infringement—given the prior art. For example, (1) Zeldis et al., disclosed combining pomalidomide with excipients (mediums for delivery) like mannitol and pregelatinized starch; (2) Remington's taught the capsule sizes claimed by the '427 that can be swallowed, and the benefits of spray-drying common diluents like mannitol; (3) McNally identified sodium stearyl fumarate as a known lubricant; and (4) Schey (June 2002) disclosed that the maximum tolerate dosage for pomalidomide was up to 5 mg/day. In other words, the claims of the '427 were expressly taught in the prior art. The examiner recognized that and rejected the patent over those same references. It was only after Celgene submitted the false Tutino Declaration that the examiner allowed the patent. The Tutino Declaration attested that the inventors had solved for unexpected stability issues. But there was nothing surprising or

otherwise sufficiently novel to warrant a patent. Thalidomide analogs, including pomalidomide, were known to be unstable due to hydrolysis. Stability issues with excipient combinations were expected and regularly addressed through routine optimization. All elements of Celgene's claimed formulation were known or obvious in light of the prior art.

306. Even if the formulation patents were somehow valid, a brand company in Celgene's position could not reasonably expect to prove that the '427 was infringed. The '427 is a simple patent claiming a finite combination of ingredients and weights. Generic companies routinely design their ANDA applications around formulation patents like the '427 to avoid infringement, a fact about which Celgene would have been well aware. Further, those patents were subject to invalidity challenges based on indefiniteness, and lack of written description and/or enablement. The generic ANDA filers made compelling arguments that a POSA, just by reviewing the claims or reading the specifications, would not have known or been able to determine with reasonable certainty whether the claimed dosage form fell within the scope of the claims.[146] In fact, Celgene had so little confidence in the '427 patent, it withdrew its infringement claims as to this patent before most, if not all, of the settlements occurred.[147]

307. If litigated to a decision on the merits, the '262, '428, '3939, and '427 patents would be found unenforceable, invalid, and/or not infringed for the reasons given above. Celgene pursued the litigation, not because it had an expectation of achieving a favorable outcome, but rather to use the litigation process itself to impede generic entry. By simply filing the lawsuit, Celgene obtained a 30-month delay during which the FDA could not grant final

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[146] *See Celgene v. Hetero*, No. 17-cv-3387 (D.N.J.), Defendants' Invalidity Contentions with Respect to U.S. Patent Nos. 8,198,262; 8,673,939; 8,735,428 and 8,828,427 at pp. 191-195 (ECF No. 922, Exhibit D).

[147] *See Celgene v. Hetero,* 17-3387 (D.N.J.), Special Discovery Master Order No. 14 dated Dec. 31, 2020 at fn. 1 (ECF No. 821) ("Celgene is not asserting the '427 patent against defendants.").

approval to any generic Pomalyst product. Celgene filed its sham lawsuits with the primary goal of securing this 30-month delay.

J. Throughout 2017, the generic manufacturers aggressively defended against Celgene's claims of infringement, with some generics filing counterclaims against Celgene.

308. After Celgene instituted the patent infringement litigation, the generic manufacturers filed answers stating that the asserted patents either would not be infringed by the generic's ANDA product or were invalid. Several of the generic manufacturer defendants also asserted counterclaims against Celgene. Celgene filed answers as to these counterclaims and in some instances filed counter-counterclaims, which precipitated another round of answers. The filing of these pleadings occupied much of 2017 and early 2018. One generic manufacturer, Mylan, took a different tact. On August 8, 2017, Mylan filed a motion to dismiss for, *inter alia,* improper venue. The court did not initially grant the motion and instead allowed the parties to engage in venue related discovery.

309. During this time, Celgene continued to work on all fronts to extend its monopoly. On July 17, 2017, the examiner granted a final determination of a patent extension for the '262 patent, moving the original expiry date from October 19, 2024, to June 17, 2025.

310. As of the end of 2017, Celgene was litigating infringement claims as to four patents (the three method of treatment patents and one formulation patent) and it was in the process of prosecuting the patent application that would eventually lead to the '467 formulation patent.

311. On December 17, 2017, the would-be generic companies filed a nearly two-hundred-page statement of invalidity contentions regarding the '262, '3939, '428, and '427 patents. In it, the generic companies argued that the four patents were either obvious or not

infringed, citing over 100 known articles, studies, and patents. Aware of the weaknesses of these patents, Celgene sought to bolster its generic blockade by acquiring even more patents.

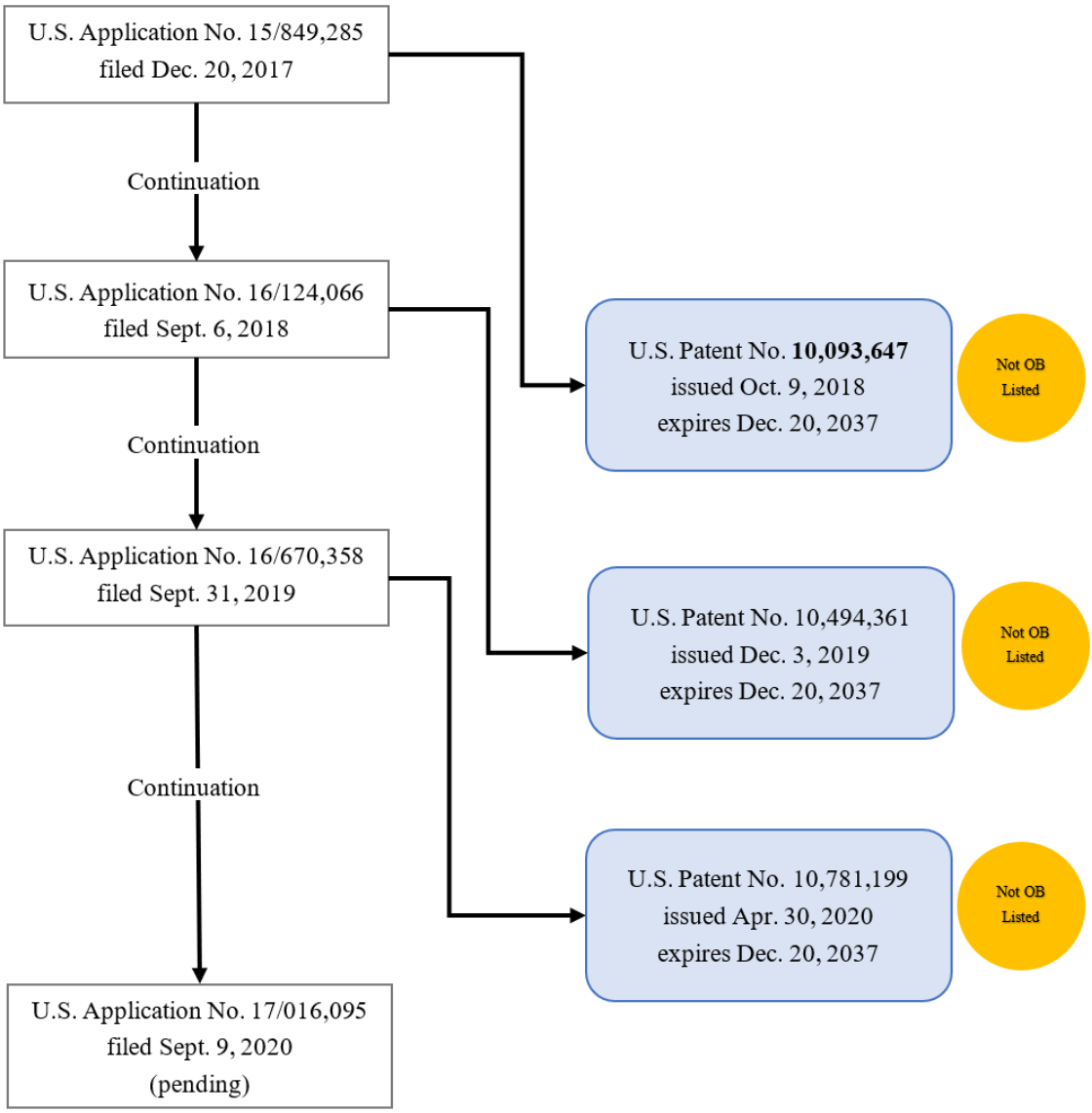
K. In late 2017, approximately nine months after receiving the paragraph IV letters, Celgene sought three new patents claiming crystal forms (the '647, '648, and '649).

312. On December 20, 2017, Celgene[148] filed three new patent applications claiming crystal forms[149], of 4-amino-2-(2,6dioxopiperidine-3-yl)isoindoline-1,3-dione, also known as pomalidomide or Pomalyst. The three patent applications would ultimately lead to the '647, '648, and '649 patents. Each of these patents derives from a separate patent application:

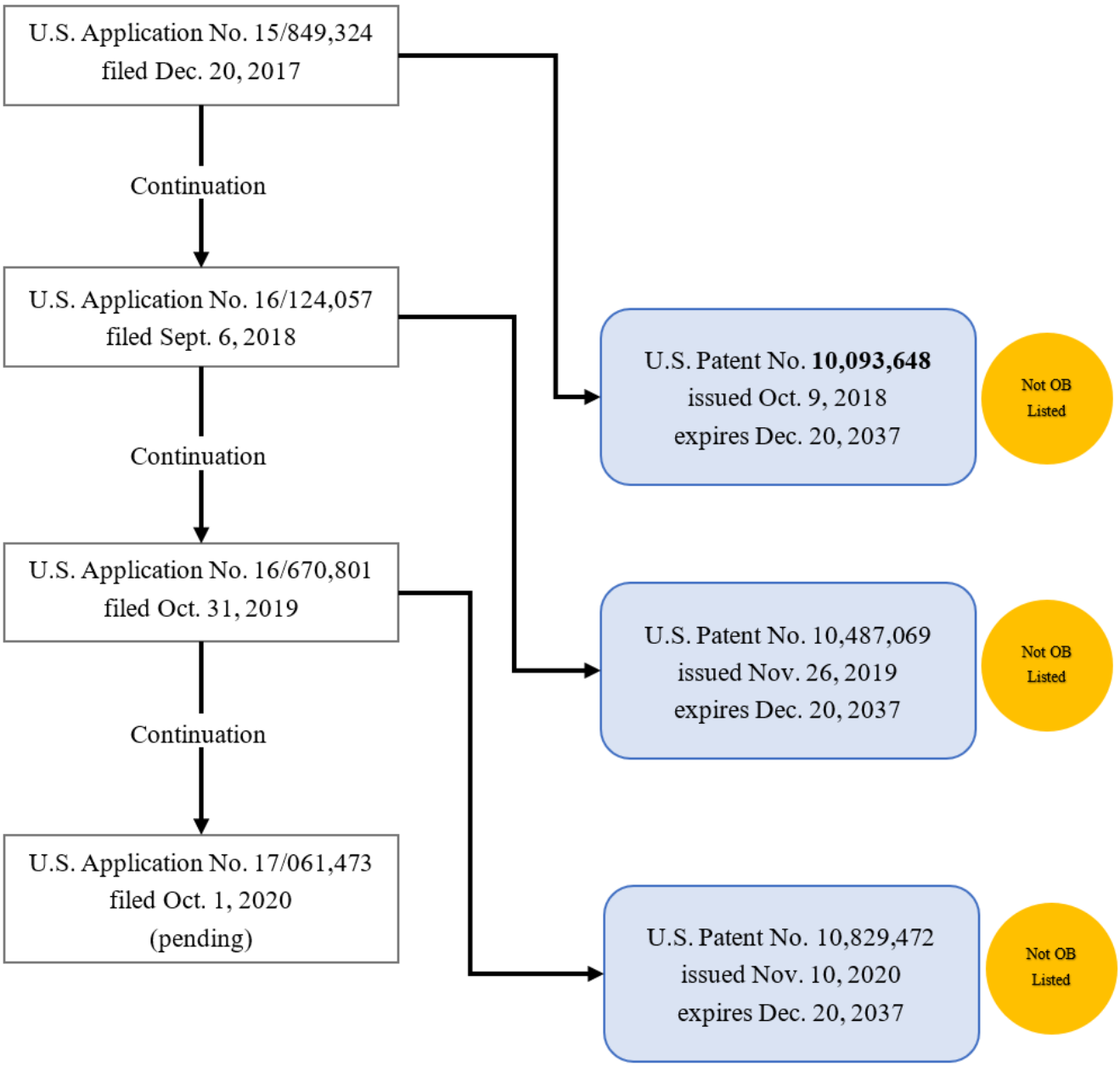
[148] The named inventor is Jerry Atwood, who subsequently assigned the patents to Celgene. To avoid confusion, the applicant for the crystal form patents is referred to here simply as "Celgene."

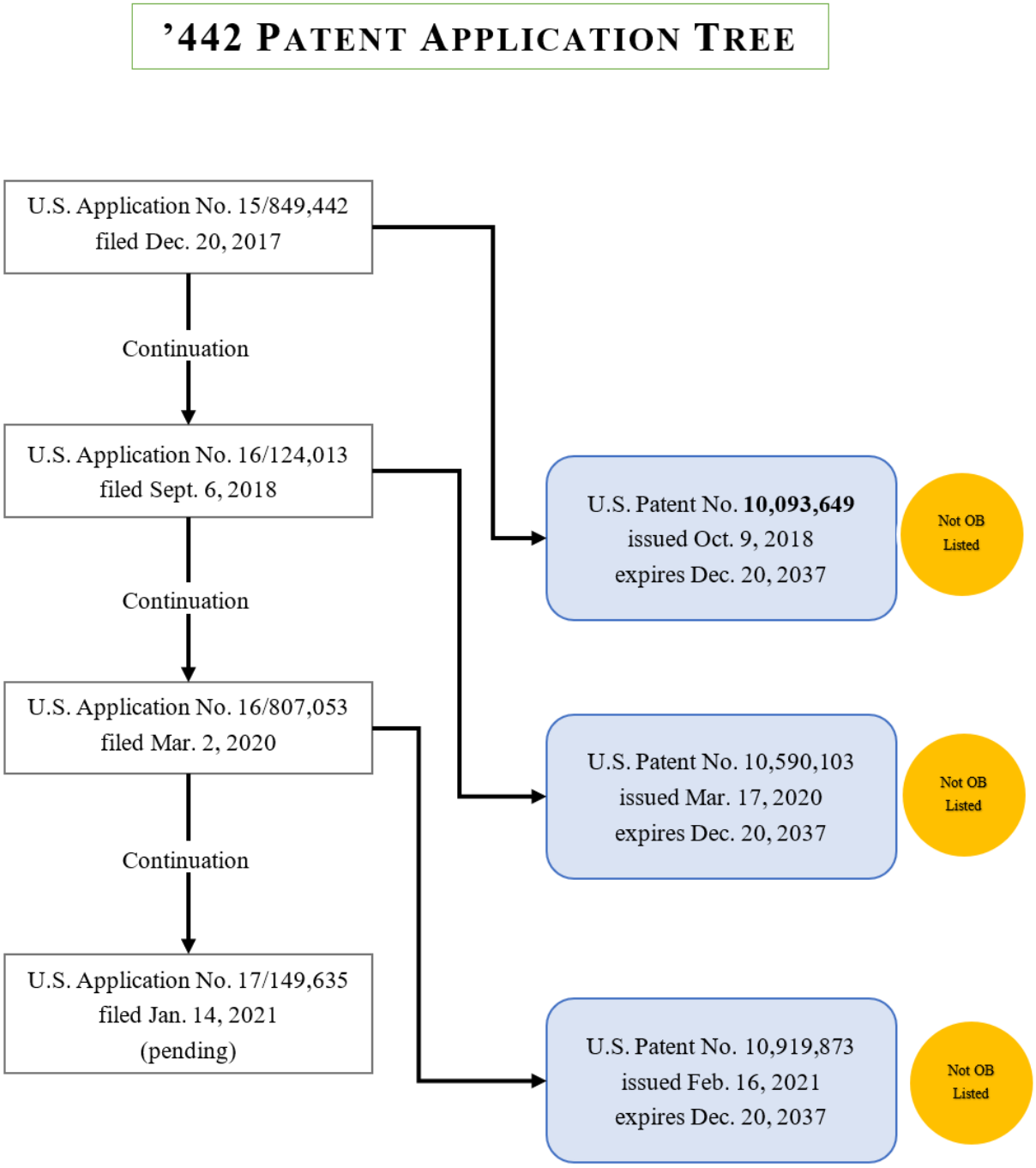
[149] Many active pharmaceutical ingredients (APIs_ can crystallize in different three-dimensional structures. Crystalline APIs with the same chemical composition but different three-dimensional structures are referred to as polymorphs. Many APIs can crystallize in hydrate and anhydrous forms. Hydrates are sometimes referred to as pseudo-polymorphs. For simplicity, we refer to polymorphs and pseudo-polymorphs as crystal forms.

'285 PATENT APPLICATION TREE



'324 PATENT APPLICATION TREE





313. The priority date for each of these patents post-dates the majority of the first filers' Paragraph IV letters, which were transmitted in March and April 2017:

Patent	Application Date	Priority Date
'647	12/20/2017	5/26/2017

Patent	Application Date	Priority Date
'648	12/20/2017	9/22/2017
'649	12/20/2017	9/22/2017

314. Each of Celgene's patents has a single independent claim, claiming a specific chemical composition and a specific crystalline form identified peaks in by an x-ray powder diffraction pattern ("XRPD").

315. Claim 1 in the '647 claims reads: "Crystalline 4-amino-2-(2,6-dioxopiperidine-3-yl)isoindoline-1,3-dione **dihydrate**, having an X-ray powder diffraction pattern comprising peaks at 13.9, 16.6, and 25.5 degrees 2θ±0.2 degrees 2θ.".

316. Claim 1 in the '648 reads: Crystalline 4-amino-2-(2,6-dioxopiperidine-3-yl)isoindoline-1,3-dione **hemihydrate**, having an X-ray powder diffraction pattern comprising peaks at 12.0, 17.2, and 25.6 degrees 2θ±0.2 degrees 2θ."

317. Claim 1 in the '649 reads: Crystalline 4-amino-2-(2,6-dioxopiperidine-3-yl)isoindoline-1,3-dione **monohydrate**, having an X-ray powder diffraction pattern comprising peaks at 11.8, 17.1, and 24.2 degrees 2θ±0.2 degrees 2θ."

318. Celgene applied for these three patents approximately nine months *after* receiving seven paragraph IV letters, which described the generic Pomalyst ANDA products in detail. Celgene would later assert these patents against the generic ANDA filers arguing infringement. It defies logic that these patents, applied for *after* the generics filed their pomalidomide ANDA applications, could be both infringed by an earlier-in-time ANDA product and simultaneously novel over the prior art. Celgene applied for these patents to create additional hurdles for generics, rather than for any legitimate purpose.

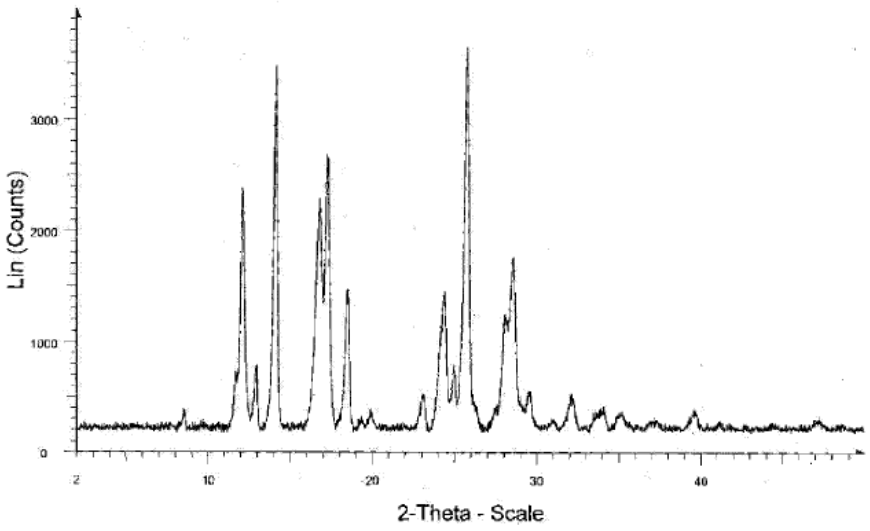
L. Celgene's crystalline form patents would have been found invalid.

319. XRPD is a common and well-known analytical method used to identify and distinguish crystalline forms of pharmaceutical compounds. The output of a PXRD experiment is typically reported as a diffractogram where the X-axis plots the scattering angle in terms of 2θ ("two theta") given in units of degrees, and the Y-axis is intensity given in either absolute units or relative units compared to the strongest peak in the diffraction pattern. The peaks present in a diffractogram are also sometimes reported in tabular rather than graphical form. An API of moderate size will typically have dozens of peaks in its XRD pattern.

320. Well before Celgene and its agents sought the crystalline patents here at issue, scientists were studying and publishing about the crystalline forms of pomalidomide. For example, on April 1, 2014, Hetero Research Foundation applied for and obtained international patent WO 2014/170909 A2, which claimed a novel process for preparing anhydrous pomalidomide, *i.e.,* a crystalline form of pomalidomide that contains no water in the crystal structure. Hetero referred to its anhydrous form of pomalidomide as "Form I."

321. Hetero Research Foundation's Form I pomalidomide was characterized with X-ray powder diffraction (XRPD).

FIGURE 1



322. This international patent, which has a priority date of April 01, 2013, issued on October 23, 2014.

323. Shortly thereafter, on October 1, 2015, Hetero Research Foundation filed the corresponding U.S. patent application (No. 14/872,743), again claiming the novel preparation process of pomalidomide crystalline Form I.

324. On December 20, 2017, Celgene filed three new U.S. patent applications. These applications claimed dihydrate ('647), hemihydrate ('648), and monohydrate ('649) crystalline forms of pomalidomide, which contain 2, 0.5, or 1 moles of water for every mole of pomalidomide, respectively.

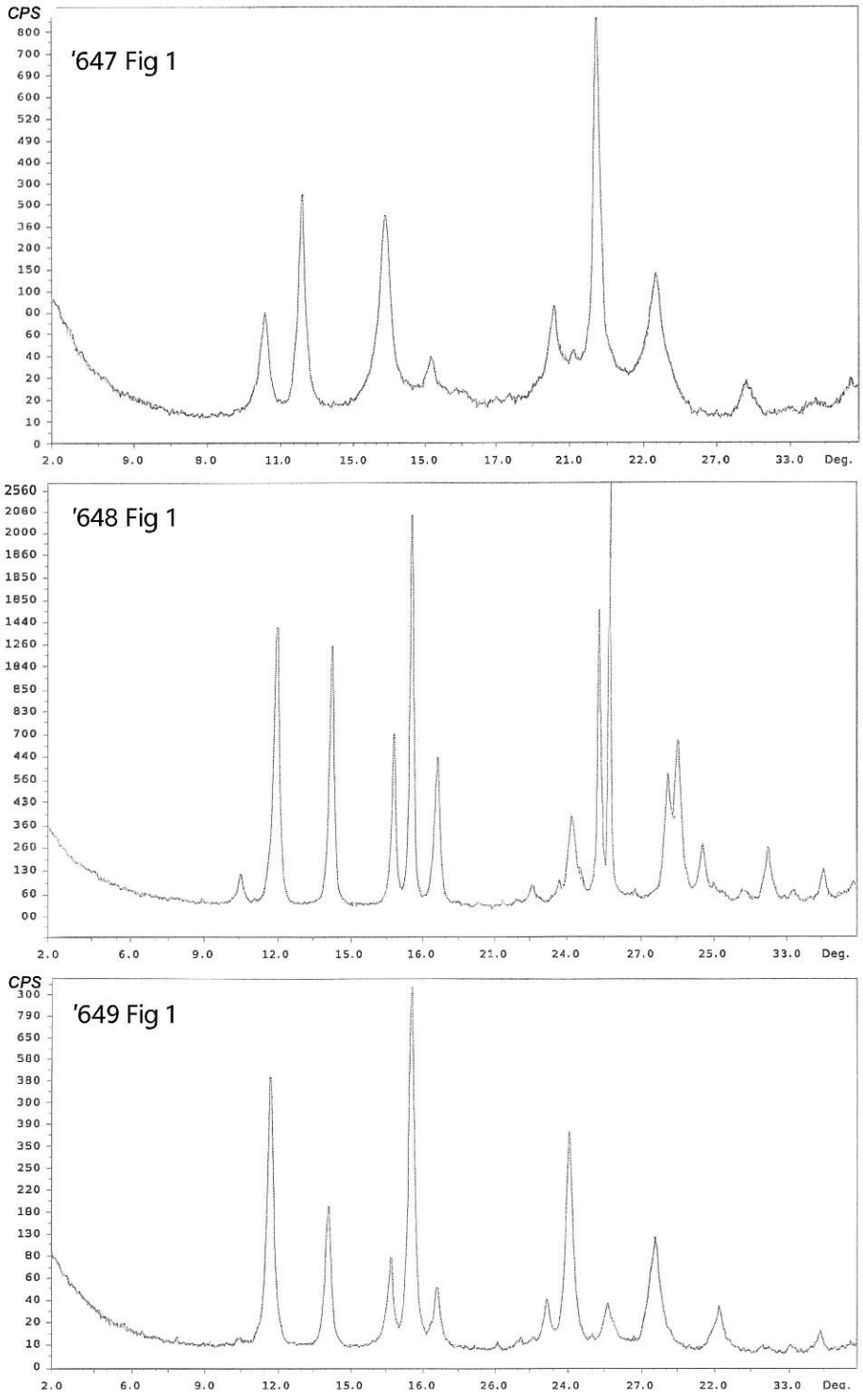
325. These patents were subject to several strong invalidity challenges.

326. First, as the generic ANDA defendants argued in the underlying infringement litigation, "Celgene's Pomalyst product and the API Celgene uses to prepare its Pomalyst

product have been marketed by Celgene since 2013—four years prior to the earliest priority date of the hydrate-patents-in-suit—and are thus prior art to the hydrate-patents-in-suit."[150]

327. Second, as the generic ANDA filers would later point out in their Markman briefing (discussed below), the X-ray powder diffraction (XPRD) patterns disclosed in these three applications were strikingly similar to one another, with substantial overlap in the claimed peaks:

[150] *Celgene v. Aurobindo*, 19-05799, Revised Joint Proposed Discovery Plan dated Aug. 19, 2019 at 15 (ECF No. 37).



328. Third, Celgene's thermogravimetric analysis (TGA) data contradicts its own claims of composition. TGA is a test used to characterize the thermal properties of crystalline

forms. It is particularly useful for hydrates since it measures weight changes as a function of temperature, such as when the application of heat causes water (and hence weight) loss. For any given hydrate composition, there is a theoretical maximum weight change due to water loss. The water content of hemihydrate, monohydrate and dihydrate forms of pomalidomide are 3.19%, 6.18% and 11.64%, respectively. But the TGA data for at least two of Celgene's purported crystalline forms exceeds the maximum theoretical values that are possible.

329. For example the maximum theoretical weight loss for pomalidomide monohydrate ('649 patent) is 6.19%. Yet, Celgene purports to have encountered several values higher than that, with one value as high as 7.4% ('649 patent at Columns 13-14):

ca. 50 mg pomalidomide Form A (anhydrate) was dissolved in a 1:1 1,4-dioxane:water solution at 85° C. The pomalidomide dissolved completely in the solution. The solution was taken to dryness on a rotary evaporator and air dried overnight. The resulting solid was found to have 6.7% water by TGA analysis.

ca. 50 mg pomalidomide Form A (anhydrate) was dissolved in a 1:1 1,4-dioxane:water solution at 80° C. The pomalidomide dissolved completely in the solution. The solution was taken to dryness on a rotary evaporator, triturated with water. The resulting solid was found to have 6.5% water by TGA analysis.

* * *

ca. 50 mg pomalidomide Form A (anhydrate) was dissolved in a 1:1 ethanol:water solution at 80° C. The pomalidomide dissolved completely in the solution. The solution was taken to dryness on a rotary evaporator. The resulting solid was found to have 7.4% water by TGA analysis.

ca. 50 mg pomalidomide Form A (anhydrate) was dissolved in a 1:1 ethanol:water solution at 80° C. The pomalidomide dissolved completely in the solution. The solution was taken to dryness on a rotary evaporator. The resulting solid was found to have 6.9% water by TGA analysis.

Similarly, for the '648 patent claiming the hemihydrate form, Celgene reports weight loss as high as 4.3%, but the maximum theoretical value is 3.2%.

330. These discrepancies call into question the validity of Celgene's crystalline form patents.

331. The generic defendants in the underlying infringement litigation made this argument directly. They pointed out that the TGA thermograms included in the crystalline form patents were "not sufficient to show that the tested samples were crystalline pomalidomide hydrates."[151] In particular, the thermograms lacked features that could distinguish between loss of crystalline water or surface water. Based on this data and related analyses, the generic ANDA filers further argued that the "Patentee did not possess crystalline pomalidomide hydrates having the water content stated [in their patents].[152]

332. Celgene's crystal form patents were also subject to additional invalidity challenges, including lack of enablement and indefiniteness.

333. On June 12, 2020, the generic defendants attached to a Notice of Motion to Amend Invalidity Contentions a preview of their invalidity arguments against Celgene's crystalline form patents. Included was an excerpt of their supplemental invalidity contentions, which argued that the asserted claims were invalid for lack of enablement because "a POSA trying to make the claimed crystalline pomalidomide hydrates would have been left to start from

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[151] *Celgene v. Aurobindo*, 17-05799, Supplemental Invalidity Contentions with Respect to U.S. Patent Nos. 10,093,647; 10,093,648; and 10,093,649 dated June 12, 2020, Ex. 1 at 4 (ECF No. 62-2).

[152] *Celgene v. Aurobindo*, 17-05799, Supplemental Invalidity Contentions with Respect to U.S. Patent Nos. 10,093,647; 10,093,648; and 10,093,649 dated June 12, 2020, Ex. 1 at 4 (ECF No. 62-2).

scratch—the specifications provided no useful guidance or examples on how to make the claimed crystalline pomalidomide hydrates or what properties they exhibit."[153]

334. On July 20, 2020, the generic defendants[154] in the pomalidomide infringement litigation filed their Markman briefing, arguing that Celgene's crystalline form patents were invalid for indefiniteness. They asserted that a POSA would not have been able to identify the specific hydrate form claimed in each patent due to vague disclosures and the substantial similarity in the XRPD peaks across the patents.[155]

335. The Markman briefing also criticized Celgene's strategy of intentionally and impermissibly drafting overly vague patent claims, allowing it to review testing data from ANDA filers and the prior art, and then tailor its infringement positions accordingly. This tactic, the generics argued, would enable Celgene to claim that its vague patent terms were not covered by the prior art but did cover the accused ANDA products.[156]

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[153] *Celgene v. Aurobindo*, 17-05799, Supplemental Invalidity Contentions with Respect to U.S. Patent Nos. 10,093,647; 10,093,648; and 10,093,649 dated June 12, 2020, Ex. 1 at 6 (ECF No. 62-2).

[154] Generic defendants included Hetero Labs Limited, Hetero Labs Limited Unit-V, Hetero Drugs Limited, Hetero USA, Inc., Aurobindo Pharma Limited, Aurobindo Pharma USA, Inc., Aurolife Pharma LLC, Eugia Pharma Specialties Limited, Apotex Inc., Mylan Pharmaceuticals Inc., Mylan Inc., Mylan, N.V., and Breckenridge Pharmaceutical, Inc.

[155] *Celgene v. Hetero*, 17-05797, Defendants' Opening Claim Construction Brief dated July 20, 2020, at 11-12 (ECF No. 86).

[156] *Celgene v. Hetero*, 17-05797, Defendants' Opening Claim Construction Brief dated July 20, 2020, at 25-26 (ECF No. 86) ("In response to Defendants' indefiniteness position, Celgene has refused to offer any definitions for the terms "corresponding to" and "about," instead asserting that no construction is necessary. The apparent reason for this is that it allows Celgene to defer taking a position on their meanings until it has testing data for the prior art and the accused products, so it can then shape its position to fit those data. At that point, Celgene can take a position that allows it to argue that claims including these vague terms do not cover the prior art but do cover the accused products.").

336. On October 12, 2020, the parties to these infringement suits filed an amended joint claim construction and prehearing statement withdrawing Celgene's claims of infringement as to many of the claims of the crystalline form patents. Less than a month later, prior to the close of discovery or expert reports, Celgene began settling with the Pomalyst ANDA filers.

M. In the Spring of 2018, Celgene pursued the '5939 formulation patent through fraud.

337. Celgene's quest to acquire additional Pomalyst patents to block generic competition continued unabated. On May 10, 2018, Celgene filed application no. 15/976,808. Celgene filed this patent application more than a year after receiving seven paragraph IV letters describing in detail the ANDA products those generic manufacturers sought to bring to market:

Generic manufacturer	Date of paragraph IV letter
Teva	March 30, 2017
Natco/Breckenridge	April 11, 2017
Apotex	March 30, 2017
Hetero	March 29, 2017
Par	April 12, 2017
Aurobindo	April 5, 2017
Mylan	April 6, 2017
Synthon/Alvogen	May 4, 2018
DRL	May 31, 2019

338. Patent application no. 15/976,808 would eventually lead to the 10,555,939. The '5939 is identical to the '467, except that the '5939 claims slightly broader ranges as compared to the '467 in two claims:

Claim no. (type)	'467	'5939
1 (independent)	1. An oral dosage form in the form of a capsule which comprises: 1) pomalidomide at an amount of 0.1 to 3 weight percent of the total weight of the composition; 2) a	1. An oral dosage form in the form of a capsule which comprises: 1) pomalidomide at an amount of 0.1 to 3 weight percent of the total weight of the composition; 2) a

Claim no. (type)	'467	'5939
	binder or filler at an amount of **90** to 99 weight percent of total weight of the composition, wherein the binder or filler is a mixture of starch and mannitol; and wherein the ratio of mannitol: starch in the dosage form is from about 1:1 to about 1:1.5.	binder or filler at an amount of **70** to 99 weight percent of total weight of the composition, wherein the binder or filler is a mixture of mannitol and starch; and wherein the ratio of mannitol:starch in the dosage form is from about 1:1 to about 1:1.5.
3 (dependent)	3. The oral dosage form of claim 1, wherein the binder or filler is present at an amount of 95 to 99 weight percent of total weight of the composition.	3. The oral dosage form of claim 1, wherein the binder or filler is present at an amount of 85 to 99 weight percent of total weight of the composition.

339. During the prosecution of this formulation patent, Celgene again tried to define the scope of the claims broadly, as it did with the prior formulation patent applications. The examiner rejected the patent application four separate times as obvious over the prior art (*i.e.,* Zeldis, Remington's, and McNally) and for double patenting.

340. Celgene again sought to overcome the examiner's obviousness rejections by resubmitting the June 17, 2013 Tutino Declaration and claiming "unexpected results." Celgene had submitted the same false and misleading Tutino declarations previously to overcome the examiners' rejections and obtain the '427 and '467 formulation patents. Although Celgene had previously succeeded in obtaining two patents based on the false Tutino declarations. the examiner for the patent prosecution that led to the '5939 was not convinced, specifically stating that the argument regarding "unexpected results" was not persuasive: "Applicant's arguments related to unexpected results were fully considered but are not persuasive for reasons of record."

341. The patent examiner ultimately allowed the patent to issue after Celgene filed a terminal disclaimer as to the '427 and '467.

342. The '5939, which was nearly identical to the '467 (differing only as to the ranges in two discrete respects), is invalid as obvious over the prior art and (as with the other formulation patents) was exceedingly easy to design around.

N. In June 2018, Celgene obtained the '467 formulation patent by fraud, prompting a wave of new sham litigation by Celgene.

343. On June 12, 2018, the '467 formulation patent issued. Although this patent did not issue until more than a year after the ANDA filings, Celgene nevertheless promptly filed new lawsuits against the generic manufacturers alleging infringement of this newly-issued patent:

Generic Manufacturer	Date Sued For Infringement of the '467
Teva	September 27, 2018
Breckenridge and Natco	October 5, 2018
Hetero	October 9, 2018
Mylan	November 11, 2018
Apotex	November 21, 2018
Aurobindo	January 4, 2019

344. While the generic ANDA filers would be compelled to defend themselves against Celgene's '467 infringement claims, the filing of these lawsuits would impose a significant burden by forcing them to divert time and resources toward litigation—resources that would otherwise be focused on securing final FDA approval and preparing for launch. Even though these lawsuits could not trigger a 30-month stay for eight of the ANDAs—since the '467 patent did not exist at the time of their filing—they would still impose costly and unnecessary delays. .A reasonable litigant in Celgene's position could not realistically expect to prevail on the merits of its lawsuits alleging infringement of the '467. The patent was obtained through the fraudulent Tutino declarations, which would have been revealed during the patent litigation. Even if not obtained by fraud, the patent would have been found invalid over the prior art. Celgene also had no hope of proving that any generic's ANDA product, let alone all of the ANDA products,

would infringe this very narrow, easy to design around patent. Celgene did not pursue the litigation with any expectation of achieving a favorable outcome. Instead, Celgene's lawsuit was motivated by the intent to use the litigation process itself to delay generic competition by creating hurdles for the generics.

O. In mid-2018, Celgene also filed patent infringement litigation against the later ANDA filer Synthon/Alvogen.

345. In May 2018, Synthon and Alvogen, which had partnered on a Pomalyst ANDA, sent their Paragraph IV letter to Celgene. Because Synthon/Alvogen were not first-filers (most generics sent their Paragraph IV letters in February 2017, approximately fifteen months earlier), Synthon/Alvogen would be precluded from entering the market until expiration of any 180-day exclusivity period awarded to (and shared by) the first-filers.

346. On June 19, 2018, Celgene filed suit against Synthon/Alvogen for infringement of four of the Pomalyst patents: the '267, '3939, '428, and '427. In November 2018, Celgene filed an amended complaint adding infringement claims as to the '467 patent.

347. For the same reasons as discussed above, a brand company in Celgene's position could not realistically expect to prevail on the merits in this infringement lawsuit, but nonetheless filed the lawsuits with the intent to use the judicial process itself to impede generic entry by Synthon/Alvogen.

P. In November 2018, the parties filed their opening claim construction briefs, previewing arguments on which Celgene's infringement claims would rise and fall.

348. On November 15, 2018, the parties filed their Opening Claim Construction briefs regarding the four patents Celgene initially sued on (the '262, '428, '3939, and '427).

349. As relevant to the three method of treatment patents, Celgene conceded that "***Patentability of the claimed methods depends upon efficacy***." Celgene was clear in this position, reiterating the point multiple times in its briefing:

- "[T]he examiner allowed the claims to issue over the prior art because the claimed methods were shown to be efficacious against MM when another therapy failed. In requiring evidence of efficacy to allow the claims to issue, the Examiner confirmed that efficacy is a required part of the claimed inventions."

- "Defendants seek to read efficacy – the very crux of the invention – out of the claims."

- "Here, '[a] method of treating multiple myeloma' requires efficacy against MM. If not, then the invention would lose its entire purpose. That is neither what the inventors intended, or what the intrinsic evidence shows."

- "Adopting Defendants' position that the preamble is not limiting, and therefore does not require efficacy, would negate the purpose of the claimed inventions."

- "[H]ere, efficacy against MM is a fundamental feature of the claimed invention."

- "Without a limiting preamble [claiming efficacy], the 'invention would have no purpose.'"

- "[H]ere, the preamble – 'a method of treating multiple myeloma' – is limiting because it is the basis upon which the Patent Office allowed the claims. The Examiner allowed each of the MM patents to issue specifically because the inventions claimed therein demonstrated efficacy against MM."

- "[T]he claims issued only because the inventors demonstrated to the Examiner that their invention was efficacious against MM."

- "Because the prosecution history makes clear that the claims would not have issued absent evidence that the claimed methods resulted in efficacy against MM, which is conveyed through the preamble, the Court should construe "a method of treating multiple myeloma" as a claim limitation."

350. In other words, to distinguish the claimed invention from the prior art, Celgene asserted that its patent claimed the *efficacious* treatment of multiple myeloma with pomalidomide. As the generic manufacturers explained in their Opening Claim Construction Brief, "Celgene seeks such a limiting construction so that it may argue during the merits phase of this case, incorrectly, that [the generic manufacturer defendants'] prior art does not anticipate or render obvious the asserted [method of treatment] patent claims because the prior art allegedly did not

disclose that administration of pomalidomide would be efficacious in treating multiple myeloma." But in arguing for this claim construction, Celgene took the position that patentability "depends upon" a finding that the patent claims the *efficacious* treatment of multiple myeloma with pomalidomide. So if the court were to find (as it later did) that the patent did *not* claim the efficacious treatment of multiple myeloma, Celgene's statements would constitute a concession that its '262 is not patentable.

Q. In late 2018 to early 2019, Celgene obtained the crystal form patents and promptly filed new sham litigation as to those three patents.

351. On October 9, 2018, the three crystal form patents (the '647, '648, and '649) issued. Celgene had not even applied for the crystal form patents until months after receiving the ANDA filers' paragraph IV letters. Celgene nevertheless promptly filed new lawsuits against the generic manufacturers alleging infringement of the newly issued crystal form patents ('647, '648, and '649):

Generic Manufacturer	Date sued for infringement of the crystal form patents
Mylan	February 14, 2019
Hetero	February 14, 2019
Natco/Breckenridge	February 14, 2019
Apotex	February 14, 2019
Teva	March 19, 2019
Synthon/Alvogen	April 12, 2019

352. Celgene's claims of infringement were doomed from the start by a catch-22 of Celgene's own making: if an earlier-in-time ANDA product would infringe one of Celgene's later-in-time crystal form patents, then the patent is invalid as anticipated and/or obvious in light of the prior art.[157]

[157] *See* 35 U.S.C. §§102, 103.

353. Further, the striking similarity among the three crystal form structures—combined with the questionable scientific data regarding the claimed water weight loss contained in each patent—would have made invalidity and/or obviousness arguments straightforward and compelling. Celgene knew this and still chose to pursue sham infringement litigation on the crystal form patents.

354. Even if the crystal form patents were somehow valid, Celgene could not expect to prevail on its infringement claims. Among other reasons, at least one ANDA product, produced by Hetero, was anhydrous, i.e., a different crystalline form from that claimed in any of Celgene's crystalline form patents. As Hetero explained in an August 26, 2020 letter to the court:

> Hetero submitted its ANDA before Celgene had even applied for patents asserted in this case. Hetero's ANDA Product uses the same anhydrous form of pomalidomide that Celgene uses in its NDA product, Pomalyst®, which is why Celgene has not listed the asserted hydrate patents in the Orange Book and why this Court previously held that Local Patent Rule 3.6 did not apply in this case and ordered Celgene to serve its infringement contentions before Hetero served its non-infringement and invalidity contentions.[158]

355. A brand company in Celgene's position could not realistically expect to prevail on its claims that the crystal form patents were valid and infringed. Rather, Celgene obtained and asserted these patents to create additional hurdles for generics, rather than for any legitimate purpose.

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[158] *Celgene Corp. v. Hetero,*19-05797, letter from Plaintiffs to Judge Hammer dated August 26, 2020, ECF No. 25 at p. 7.

R. In the Spring of 2019, a new generic manufacturer, Dr. Reddy's, sought to enter the market with generic pomalidomide, and Celgene sued it for infringement to block its entry.

356. On March 29, 2019, Dr. Reddy's filed an ANDA for generic Pomalyst. Like Synthon/Alvogen, Dr. Reddy's was not one of the first filers and therefore would not be able to enter the market with generic Pomalyst until after expiration of any 180-day exclusivity period awarded to the first filers.

357. On May 31, 2019, Dr. Reddy's sent written notice of its paragraph IV certification to Celgene.

358. On July 12, 2019, Celgene sued Dr. Reddy's for infringement of the '262, '3939, '428, '427, and '467.

359. For the same reasons as discussed above, a brand company in Celgene's position could not realistically expect to prevail on the merits in this infringement lawsuit. Celgene nonetheless filed the lawsuits with the intent to use the judicial process itself to impede generic entry by Dr. Reddy's.

S. In August 2019, the first-to-file generic manufacturers missed a regulatory deadline that put them at risk of forfeiting their 180-day exclusivity.

360. To avoid forfeiture of the right to the 180-day statutory exclusivity, the group of generic companies—Teva, Natco/Breckenridge, Apotex, Hetero, Par, Aurobindo, and Mylan—that had filed their ANDAs on the first available date (February 8, 2017) were required (subject to a rare exception) to obtain tentative or final approval of their application from the FDA by August 8, 2019.

361. However, by August 8, 2019, none of the first filers had received tentative approval. The FDA (in later regulatory filings) had noted the failure to do so, but the FDA left for later determination a final decision on whether forfeiture had occurred.

362. As a result, all of the first filing generics were at significant risk of having forfeited their 180-day exclusivity.

T. In February 2020, Celgene obtained the '5939 formulation patent by fraud, leading Celgene to yet another wave of sham litigation.

363. On February 11, 2020, the '5939 formulation patent issued. Although this patent did not exist until *three years after* the ANDAs were filed,[159] Celgene nevertheless initiated a new wave of patent litigation, filing substantially identical complaints alleging infringement of the '5939 against the following generic manufacturers on March 10, 2020: Apotex; Natco/Breckenridge; Hetero; Aurobindo; Mylan; Teva.

364. The '5939, a continuation of the '427 and '467 formulation patents, is invalid as obvious considering the prior art, including Zeldis, Remington's, and McNally. The patent examiner expressly stated it was not persuaded by the Tutino Declaration's assertion of "unexpected results." The '5939 only issued after Celgene filed a terminal disclaimer as to the '427 and '467.

365. The '5939 litigation was subjectively and objectively baseless. Celgene could not hope to prevail on its infringement claims regarding this patent. As with the '427 and '467, the '5939 was a simple patent that generics would readily design around to avoid infringement, something Celgene, as an experienced pharmaceutical company, would have understood and expected. With nine different generics seeking to bring generic Pomalyst to market, Celgene could not expect to prove that anyone, let alone all nine, ANDA products infringed this simple patent.

[159] The ANDAs not only predate the issuance of the '5939, they predate the filing of the original application that led to the '5939 patent.

366. Even if Celgene could prove infringement, it knew that its family of formulation patents were obtained based on the fraudulent Tutino declarations and was unenforceable. Celgene pursued the litigation, not because it had a reasonable expectation of prevailing on the merits, but with the intent to impede and prevent generic competition.

367. Celgene filed iterative lawsuits, not because it believed it could or would prevail in the patent litigation, but rather to interfere with the generics' attempt to gain market entry and to thwart competition.

U. In 2020, Celgene's campaign to block generic competition suffered a series of setbacks, as the generic manufacturers scored key wins in the patent litigation.

368. By Spring 2020, the original Pomalyst patent litigation had been pending for approximately three years. During this time, the parties filed a number of briefs related to claims construction, *i.e.,* determining the definitions of disputed patent terms. In addition, Mylan and Celgene had engaged in venue related discovery and, on April 13, 2020, Mylan renewed its motion to dismiss for, *inter alia,* improper venue.

369. On June 16, 2020, the court issued its Claim Construction Order.[160] The order addressed four disputed terms in the three method of treatment patents (the '262, '428, and '3939) and the three formulation patents (the '427, '467, and '5939).

370. With respect to the method of treatment patents, the parties disputed *inter alia* whether the preamble of the method of treatment claims, specifically the phrase "A method of treating multiple myeloma," should be construed as limiting the claims.[161] Celgene argued that "the phrase 'treating multiple myeloma' in the preamble limits the claim by requiring efficacy in

[160] *Celgene v. Hetero,* No. 17-3387, 2020 WL 3249117, *2 (D.N.J.)(ES)(MAH).

[161] *Celgene v. Hetero,* No. 17-3387, 2020 WL 3249117, *4 (D.N.J.)(ES)(MAH).

patients who received pomalidomide."[162] The generic manufacturers argued that the claims were not limited to the efficacious treatment of multiple myeloma, claiming only the administration of the compound as described in the claims.

371. The dispute is of central importance to the validity of the method of treatment patents, as Celgene would argue at the merits phase of the case that the claimed invention was not anticipated or obvious over the prior art because the prior art did not disclose that pomalidomide would be efficacious in the treatment of multiple myeloma. In its effort to persuade the court that the method of treatment patents were limited to the *efficacious* treatment of multiple myeloma, Celgene argued that the "[p]atentability of the claimed methods depends upon efficacy."[163]

372. The court rejected Celgene's interpretation, agreeing with the generic manufacturers that the method of treatment claims were not limited to the *efficacious* treatment of multiple myeloma: "While the Court agrees that the dispute term, 'treating multiple myeloma,' must be construed in its entirety*, nothing in the claim language, the specification, or the prosecution history warrants reading into the claim an efficacy limitation based on the preamble.*"[164]

373. The ruling eliminated any question that the method of treatment patents are invalid, as Celgene itself had conceded that patentability depended upon the claims being limited to the efficacious treatment of multiple myeloma.

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[162] *Id.*

[163] *Celgene v. Hetero,* No. 17-3387 (D.N.J.), Celgene Opening Markman Brief, at 11; *see also* ¶242, *supra.*

[164] *Id.* at *5.

374. Shortly after the court's Markman Decision, the court granted Mylan's motion to dismiss for improper venue.[165]

375. As 2020 continued, Celgene suffered additional setbacks in its generic exclusion scheme.

V. Fall of 2020—Generic entry for pomalidomide should have been imminent.

376. By the fall of 2020, generic entry for pomalidomide in the United States should have been imminent.

377. First, the NCE exclusivity period for Pomalyst had long since expired (in February 2018). As a result, the FDA was not barred from granting final approval due to NCE exclusivity.

378. Second, as to those generic companies who shared first-to-file ANDA status (having all filed on the first available date of February 8, 2017), the 30-month stay of ANDA approval passed in August of 2020. As a result, there was no longer a regulatory bar to the FDA granting final approval for generic Pomalyst.

379. Third, in October 2020 five of Celgene's Orange Book listed patents (the REMS patents) expired, eliminating any arguable issues those patents ever presented to generic entry.

380. Fourth, on October 30, 2020, FDA granted final approval to the Aurobindo and Natco/Breckenridge ANDAs. This meant that there were no longer any FDA-imposed regulatory barriers preventing Aurobindo or Natco/Breckenridge from launching its generic product immediately.[166]

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[165] *Celgene v. Mylan,* No. 19-cv-5802, 2020 WL 12570814 (D.N.J. Sept. 25, 2020).

[166] Whether these generics would be entitled to the 180-day exclusivity period was an open question. As FDA noted in the final approval letters, Aurobindo and Natco/Breckenridge had

381. Fifth, Celgene's Pomalyst patent portfolio was riddled with fraudulently obtained patents, patents that were in all likelihood going to be held invalid or not fringed in the various sham lawsuits Celgene had filed.

382. Sixth, the market dynamics for Pomalyst presented what should have been a significant likelihood of imminent generic entry for any generic company. Pomalyst was selling over $2 billion a year, making it a highly desirable market for generic entry. While both Natco/Breckenridge and Aurobindo shared first-to-file status with other generics, those other generics had not yet received final FDA approval, opening an opportunity of *de facto* generic exclusivity for the first entrant or entrants. And while entry before conclusion of the patent litigation would require at-risk entry, those risks here were minimal (if not non-existent), and at-risk entrants, in any event, typically pay less in damages than what they earn during at-risk launch.[167]

383. In short, as early as of October 2020 Celgene should have faced imminent pomalidomide generic competition and, with that, the loss of its $2 billion Pomalyst franchise.

W. November 2020—the Celgene-Natco reverse payment agreement.

384. Rather than allow lawful competition in the U.S. market for pomalidomide, starting in November 2020, Celgene and Bristol Myers began a serial scheme to pay off its would-be pomalidomide competitors to have them delay generic entry for about six years, until early 2026.

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failed to get tentative approval within 30 months of filing its ANDA, potentially jeopardizing their 180-day exclusivity period. FDA deferred a decision on the 180-day exclusivity question until such time as another first filer became eligible for final approval.

[167] Keith M. Drake, Robert He, Thomas McGuire, and Alice K. Ndikumana, *No Free Launch: At-Risk Entry by Generic Drug Firms*, NBER Working Paper No. 29131, August 2021, JEL No. D22, I11, I18,O32, available at https://www.nber.org/system/files/working_papers/w29131/w29131.pdf (last accessed June 20, 2025).

385. In about late October or early November 2020, Celgene and Bristol Myers, on the one hand, and Natco and Breckenridge, on the other, settled the pending pomalidomide litigation between them under terms that provide for a large, unjustified payment from Celgene/Bristol Myers to Natco/Breckenridge. In return, Natco/Breckenridge agreed to delay entry into the U.S. pomalidomide market until six years later, *i.e.*, on a date timed to have all the first filing generics have the same agreed entry date (which became the first quarter of 2026).

386. The terms of the arrangement were in part reflected in documentation, but also by the combined effect of incentives created by the agreements and industry economics. This complaint refers to the Pomalyst settlement agreement between Celgene/Bristol Myers and Natco/Breckenridge as the "Celgene-Natco agreement."

387. The Celgene-Natco agreement does not represent a *bona fide*, arms-length resolution of the merits of the pomalidomide litigation. The generic Pomalyst entry date agreed to by Natco/Breckenridge and Celgene was an integral part of, and the result of, the enormously lucrative agreement Natco and its commercial partners had reached with Celgene to share supracompetitive profits for Revlimid and lenalidomide sales until early 2026, as described in detail below.

388. *First*, the facts of the existing patents and litigation show that the Celgene-Natco agreement is not based on the merits of the patent dispute; Natco/Breckenridge had little reason to settle, and certainly not on terms where market entry is delayed until early 2026.

389. At the time of settlement, Celgene had nine unexpired pomalidomide patents: the three method of treatment patents ('262, '3939, '428), the three crystal form patents ('647, '648, '649), and the three formulation patents ('427, '467, '5939).

390. As to the three method of treatment patents, Celgene had no colorable basis to prosecute to conclusion infringement litigation based on them (as previously alleged), and all

three were to expire *before* the agreed entry date (of the first quarter of 2026). As a result, the method of use patents cannot explain a delay into 2026.

391. As to the three crystal form patents, Celgene had no colorable basis to prosecute to conclusion infringement litigation based on them. (As previously alleged, these patents were applied for *after* the generic companies had developed their ANDA products and served paragraph IV notices; it could not be the case that both the generics' products infringed the crystal form patents and that the crystal form patents were not obvious over the prior art, *i.e.*, the ANDAs). Celgene had no ability to protect its pomalidomide franchise against the filed ANDA applicants with these patents.

392. As to the three formulation patents, one of those patents (the '427 formulation patent) was withdrawn from litigation by Celgene (at least by December 2020). Because Celgene could not prosecute patent infringement litigation based on it, that patent cannot explain the 2026 agreed entry date.

393. The remaining two formulation patents—the '467 and the '5939—were both set to expire on May 19, 2030. That date, extending as it does into the future, is quite telling. Celgene did not even bother to apply for these patents until well after all or nearly all the Pomalyst ANDAs were filed (in the case of the '5939, approximately *three years* later). The notion that these patents are somehow essential to Pomalyst (and thus capable of blocking generic entry) is not credible. In any event, both patents were obtained based on the fraudulent Tutino declarations and are therefore unenforceable, as well as invalid as obvious over the prior art. The claims of the formulation patents are also quite narrow and would be easy for a generic manufacturer to design around.

394. *Second*, Celgene protected Natco/Breckenridge's risk of forfeiting their 180-day statutory exclusivity. As alleged above, Natco/Breckenridge had failed to obtain tentative or final

approval within 30 months—which put them at risk of forfeiting their 180-day exclusivity. Celgene knew of this potential forfeiture. As such, Celgene and Natco/Breckenridge agreed to remove the risk of competition that would ensue if the FDA determined that one or more first filers forfeited by conferring contractual exclusivity on Natco/Breckenridge. Although a year later, on December 6, 2021, the FDA determined—in its letter granting tentative approval to Dr. Reddy's—that the first filers had not forfeited their 180-day exclusivity; that does not change the fact that, a year earlier, Celgene and Natco/Breckenridge had already protected that forfeiture risk through their anticompetitive settlement agreement.

395. *Third*, Natco received a reverse payment totaling hundreds of millions of dollars, in linked Revlimid patent settlements. The linked Revlimid settlements are described more fully below in Section V.Z.3.

396. Finally, the facts surrounding the non-disclosure of the settlement also show that the Celgene-Natco agreement contains an anticompetitive reverse payment.

397. Under the settlement, the parties apparently agreed to keep secret *all* the specific terms of the settlement, even the agreed entry date, for some period. For example, during earnings call on November 13, 2020, analysts repeatedly pressed Natco's CEO Rajeev Nannapaneni for the most basic information about the terms of the settlement. The CEO declined to provide any information, stating at one point, "I already answered the question, but I will just repeat it one more time. . . . we will not disclose the [generic launch] date because the settlement agreement was very particular that we do not talk about the date."

398. The parties kept the entry date secret for about a year and a half. Eventually in February 2022 —and only after settling with all the other would-be pomalidomide generic entrants—Bristol Myers disclosed the entry date to the public. There would be no generic entry into the pomalidomide market until the first quarter of 2026: "As it relates to U.S. IP for

Pomalyst, we are pleased that there is now no outstanding litigation. At this point, we don't expect generic entry in the U.S. market prior to the first quarter of 2026."

399. The publicly disclosed terms of the Celgene-Natco agreement are the facts that (i) the parties settled all pomalidomide litigation between them, (ii) the agreed entry date would be in the first quarter of 2026, and (iii) that there are other terms of the agreement, but the parties refuse to disclose them to the public.

400. To settle Hatch-Waxman patent litigation, it is sufficient for the parties to settle based on an agreed entry date, and nothing more. In fact, the Federal Trade Commission (FTC) published a study finding that from 2004 through 2009, seventy percent of final settlements agreements (152 out of 218) "did not involve compensation from the brand to the generic combined with a delay in generic entry." As the FTC explained, "[t]his large number of settlements not involving compensation from the brand to the generic undermines brand and generic firms' arguments that compensation is the only way to settle patent litigation. In fact, there are a variety of ways to settle litigation that do not involve these payments."[168] In settling based on an agreed entry date and only an entry date, the settlement is likely assured to be based on the relative merits of the parties' positions in the underlying patent litigation. But when the parties add additional consideration going to the settling generic in the agreement, the likelihood is that non-patent-merits considerations are influencing the agreed entry date.

401. Here, the Celgene-Natco agreement contains provisions other than the agreed entry date, and the parties seek to conceal those other terms. Taken in the context of all other facts, this further shows that the Celgene-Natco agreement provides a large, unjustified payment to the Natco parties. While the settling parties to the Celgene-Natco agreement have had some

[168] FTC Pay-for-Delay Study.

success keeping the specific *form* of the reverse payment secret, they have not been able to conceal the *existence and size* of the reverse payment in the November 2020 agreement. Additional information regarding the exact size of the reverse payment has come to light following the market entry for limited volumes of generic Revlimid, as described further below.

402. Finally, the likelihood of anticompetitive provisions in the Celgene-Natco agreement is shown by the fact that similar agreements between Celgene and Natco have failed review by competition authorities outside the U.S., authorities that apply competition principles similar to those in the U.S.

403. On December 3, 2021, Celgene and Natco submitted settlement/licensing agreements for Pomalyst and Revlimid to the Australian Competition and Consumer Commission (ACCC) for approval. On March 23, 2022, the ACCC issued a Draft Determination recommending rejection of the application, stating the "ACCC considers the settlement and license agreement is likely to result in public detriment by reducing competitive tension in relation to generic entry in the supply of lenalidomide and pomalidomide. The ACCC considers the settlement and license agreement provides Celgene with greater control and certainty over the timing of generic entry by Juno/Natco, seeks to confer on Juno/Natco a 'first mover advantage', may deter other generic entry, [REDACTED]." On July 29, 2022 (the eve of the deadline for the ACCC's final determination), Celgene and Natco withdrew their application. One report about the incident wrote "the ACCC's draft determination marks one of the first opportunities the regulator has had to consider a reverse payment settlement in the Australian context — and is likely to have a chilling effect on similar applications for the foreseeable future."

404. The *de facto* payment to Natco/Breckenridge is large, with a floor of $150 to $300 million (and estimated to be many times greater, based now-available public information, as set forth in Section V.Z.3, *infra*).

405. The floor can be estimated as follows. Under normal market conditions, after several months of *bona fide* generic entry, the generic penetration rate is typically 90%. If the only ANDA generic to enter the market was Natco/Breckenridge, a single first filer with 180 days of exclusivity would expect to take roughly half of those generic sales (with the other half of generic sales going to the brand company's authorized generic product, which for conservative purposes we assume would enter). Facing competition from the brand product and the authorized generic, the generic product is typically priced at approximately 60% of the brand price. Applying those figures to the pomalidomide market, during the first six months, a generic company with exclusivity would expect sales of about $300 million ($2.25 billion in 2021 U.S. sales x 0.5 years x 90% of the market is generic x 50% of generic market x 60% price of the brand).

406. Even if both Natco/Breckenridge and Aurobindo (the two companies with final ANDA approvals as of November 2020) were to enter the market (thereby sharing the 180-day exclusivity period), the revenues from the generic products would be divided by a third each (the two ANDA generic products and the authorized generic product). In addition, the presence of an additional generic would likely have caused some degree of additional price erosion. However, each of the ANDA filers would still expect to earn about $167 million ($2.25 billion in 2021 U.S. sales x 0.5 years x 90% of the market is generic x 33% of generic market x 50% price of the brand).

407. As a result, a reasonable company in the position of Natco/Breckenridge in November 2020, having first-to-file status and being one of only two finally approved ANDA

applicants, would expect to achieve about $167 to $300 million in revenues over six months were it to launch generic pomalidomide and exploit a period of oligopolistic pricing.

408. On the other hand, because of the reverse payment in the Celgene-Natco agreement settlement with Celgene, Natco/Breckenridge agrees to wait six years and not launch its approved ANDA pomalidomide product until early 2026. At that time, the market expectation is that all or most of the *other* first-to-file generics would by then have obtained their final ANDA approvals. And as this was a classic, post-NCE pile-on (where multiple generics file ANDAs on the first allowed date, and at least seven generics filed on the same date with first-to-file status), the expectation would be that, after waiting six years to enter in early 2026, the entry by Natco/Breckenridge would occur into an immediately, fully genericized market.

409. In a fully genericized market, generic penetration is about 90%, the price discount is often about the same (or larger), and most generics estimate similar shares of the market. Even assuming the pomalidomide market would grow at 5% a year, by waiting for six years to enter in the first quarter of 2026, a reasonable company in the position of Natco/Breckenridge would expect to achieve about $19.4 million over six months (projected $3.02 billion in 2026 U.S. sales x 0.5 years x 90% of the market is generic x 0.143 (i.e., 1/7th of the generic market[169]) x 10% of the brand).

410. The enormous difference between the reasonably estimated returns under these circumstances ($167-$300 million over the first six months from imminent launch, versus about $19.4 million under the settlement and six years later) requires significant compensation to Natco/Breckenridge for the settlement.

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[169] The 1/7 figure is based on there being seven generic products, *i.e.,* six ANDA products, plus an AG, which Celgene would launch under competitive conditions. To clarify, there were seven first filers, but Par withdrew its paragraph IV certification early on, leaving 6.

411. Celgene-made a large, anticompetitive, reverse payment to Natco to induce Natco to delay launch of pomalidomide into the U.S. market. That payment included an agreement by Celgene to share monopoly profits on Revlimid with Natco. In return for a share of Revlimid monopoly profits (and as necessary to *protect* the Revlimid monopoly profits), Natco agreed to delay generic Pomalyst entry to coincide with the end of the Revlimid monopoly profit share. As detailed further below in Section V.Z.3., the value of the reverse payment to Natco from the Revlimid monopoly profit share is estimated to be $660 million based on publicly available sources.

X. March 2021—the Celgene-Teva reverse payment agreement.

412. In or about March 2021, Celgene and Bristol Myers, on the one hand, and Teva defendants in the underlying infringement litigation, on the other, settled the pending pomalidomide litigation between them under terms that provide for a large, unjustified payment from Celgene/Bristol Myers to Teva. In return, Teva agreed to delay entry into the U.S. pomalidomide market until six years later, *i.e.*, the first quarter of 2026. The terms of the arrangement were in part reflected in documentation, but also by the combined *de facto* economics of the industry and incentives created by the agreement. This complaint refers to the Pomalyst settlement agreement between Celgene/Bristol Myers and Teva as the "Celgene-Teva agreement."

413. Under the Celgene-Teva agreement, the value of the payment from Bristol Myers/Celgene to Teva is substantial, certainly magnitudes larger than Celgene's avoided litigation expenses, and likely well into the nine figures.

414. Several facts, when viewed together, reveal the existence of a large, unjustified payment from Celgene/Bristol Myers to Teva. *First*, Celgene's patents (several of which expire

before the agreed-to entry date or were withdrawn prior to settlement) are weak and cannot explain the extended delay in generic entry.

415. *Second*, Teva (through its affiliate Arrow, which partnered with Natco on Revlimid) received a reverse payment estimated to be $770 million in the form of a Revlimid monopoly profit share, as detailed further below in Section V.Z.3.

416. *Third*, although Teva and Celgene settled their Pomalyst dispute by early March 2021, all information, including even the fact of settlement, was concealed for nearly a year. When the Pomalyst settlements were finally announced by Bristol Myers in February 2022, it was revealed that all generics, including Teva, had agreed to delay their entry date until the first quarter of 2026.

417. *Finally*, Teva adhered to the secret agreement, refraining from launching generic Pomalyst, despite receiving FDA final approval on May 4, 2022.

418. The Celgene-Teva agreement contains provisions other than the agreed entry date, but the parties seek to conceal those other terms. Taken in the context of all other facts, the concealment further shows that the Celgene-Teva agreement provides a large, unjustified payment to the Teva parties. While the settling parties to the Celgene-Teva agreement have had some success keeping the specific form of the reverse payment secret, they have not been able to conceal the existence of a substantial reverse payment.

Y. Spring 2021—the Celgene-Aurobindo reverse payment agreement.

419. On or about July 16, 2021, Aurobindo (which like Natco/Breckenridge had received final approval on October 30, 2020) and Celgene notified the court that they had resolved their dispute as to the Pomalyst patents. (Aurobindo had earlier discontinued its ANDA).

420. Celgene and Bristol Myers, on the one hand, and the Aurobindo defendants in the underlying infringement litigation, on the other, settled the pending pomalidomide litigation between them under terms that provide for a large, unjustified payment from Celgene/Bristol Myers to Aurobindo. In return, Aurobindo agreed to delay entry into the U.S. pomalidomide market until six years later, which according to Celgene's public statements is first quarter of 2026.

421. The terms of the arrangement were in part reflected in documentation, but also by the combined *de facto* economics of the industry and incentives created by the agreements. This complaint refers to the Pomalyst settlement agreement between Celgene/Bristol Myers and Aurobindo as the "Celgene-Aurobindo agreement."

422. The Celgene-Aurobindo agreement does not represent a *bona fide*, arms-length resolution of the merits of the pomalidomide litigation. The generic Pomalyst entry date agreed to by Aurobindo and Celgene was an integral part of, and the result of, the enormously lucrative agreement Aurobindo had reached with Celgene to share supracompetitive profits for Revlimid and lenalidomide sales until early 2026, as described in detail below.

423. Under the Celgene-Aurobindo agreement, the value of the payment from Bristol Myers/Celgene to Aurobindo is substantial, certainly magnitudes larger than Celgene's avoided litigation expenses, and likely well into the nine figures.

424. The publicly disclosed facts, particularly when viewed together, show the existence of a large, unjustified payment from Celgene to Aurobindo. *First*, again as described above, Celgene's patents (several of which expire before the agreed-to entry date or were withdrawn prior to settlement) are weak and cannot explain the extended delay in generic entry.

425. *Second*, Celgene protected Aurobindo's risks of forfeiting its 180-day statutory exclusivity. As alleged above, Aurobindo had failed to obtain tentative or final approval within

30 months—which put it at risk of forfeiting its 180-day exclusivity. Celgene knew of this potential forfeiture. As such, Celgene and Aurobindo agreed to remove the risk of competition that would ensue if the FDA determined that one or more first filers forfeited, by conferring contractual exclusivity on Aurobindo. Although the FDA stated six months later that the first filers had not in fact forfeited their 180-day exclusivity (in its letter granting tentative approval to Dr. Reddy's), Celgene and Aurobindo had already protected that forfeiture risk through their anticompetitive settlement agreement.

426. *Third*, Aurobindo received a reverse payment in the form of shared monopoly profits on Revlimid totaling hundreds of millions of dollars. As detailed further below in Section V.Z.3, the value of the reverse payment in the linked Revlimid settlements for Aurobindo can be estimated at least $160 million from publicly available sources, and likely much more.

427. Aurobindo and Celgene ended their disputes regarding Revlimid and Pomalyst *on the same day,* filing consent decrees in both matters on July 16, 2021. Aurobindo and Celgene have concealed the terms of both agreements. However, to the extent the terms of other Revlimid settlements have been disclosed, all provide for volume-limited license agreements, capping the generic's lenalidomide sales until the first quarter of 2026 (when generic Pomalyst entry begins). The Revlimid market share profit-split is worth substantial sums to Aurobindo, likely in the nine figures.

428. The circumstances surrounding Aurobindo's receipt of final approval for generic Pomalyst (on October 30, 2020) and subsequent actions confirm that it received a large, unjustified payment to delay its launch of generic Pomalyst. Had Aurobindo launched immediately, it would have earned between $167 to $300 million in the first six months alone. Instead, Aurobindo agreed to delay market entry for six years. This means that, absent some other terms to compensate Aurobindo, Aurobindo would earn approximately $19.4 million over

the first six months of entry if launching into a fully genericized market in 2026. A reasonable generic manufacturer in Aurobindo's position would not forgo these profits unless it was receiving something sizeable in return.

429. *Fourth*, the Celgene-Aurobindo agreement contains provisions other than the agreed entry date, but the parties seek to conceal those other terms. Taken in the context of all other facts, the concealment further shows that the Celgene-Aurobindo agreement provides a large, unjustified payment to the Aurobindo parties. While the settling parties to the Celgene-Aurobindo agreement have had some success keeping the specific form of the reverse payment secret, they have not been able to conceal the existence of a substantial reverse payment.

Z. Celgene provided unlawful reverse payments in the form of shared monopoly profits on Revlimid that induced generic ANDA filers to delay entry for generic Pomalyst (and generic Revlimid).

430. Although Revlimid was marketed first, Revlimid and Pomalyst were developed concurrently. Both are thalidomide analogs that are used in the treatment of multiple myeloma. Although they do not have identical approved indications, they are used for overlapping treatments.

431. When the parties to the Revlimid patent litigation settled, the agreements were not just for a particular entry date. Rather, Celgene allocated small portions of the Revlimid market to each of the settling generic Revlimid manufacturers (also referred to as volume limited licenses). Restricting the volume that a generic manufacturer can sell assures that after entering the market, the generic will maintain its pricing at supracompetitive levels. (If one cannot gain sales by lowering price, there is no incentive to compete on price.) That is exactly what happened when generic manufacturers entered the market with limited-volume quantities of generic Revlimid, as described in detail below.

432. All Pomalyst ANDA filers have a volume limited license for Revlimid.[170] All Pomalyst ANDA filers therefore share in the monopoly profits on Revlimid and generic Revlimid sales. All Pomalyst ANDA filers have agreed to delay the launch of generic Pomalyst until—and to coincide with—the end of the monopoly profit share for Revlimid. By delaying the launch of generic Pomalyst, Celgene and the generic manufacturers maximize and protect the reverse payments in the form of shared monopoly profits on Revlimid and lenalidomide. Those profits are estimated to be well into the nine figures for each of the generic manufacturers, as described below. Had generics not delayed their Pomalyst launches, the sale of generic Pomalyst would have eliminated or vastly undercut the generics', and Celgene's, supracompetitive profits on Revlimid and generic Revlimid.

433. Stated differently, Celgene was able to delay generic Pomalyst using payment in Revlimid agreements because the mechanism used to transfer the reverse payments in Revlimid—supracompetitive sales enabled by an output restriction—functionally made full payment of the reverse payment in Revlimid deals contingent on delaying their generic Pomalyst launch until expiration of the output restriction. The linked nature of the Revlimid and Pomalyst agreements is both evident from and a function of the payment/enforcement mechanism: the moment the generics stop getting paid in allocated generic Revlimid profits (January 31, 2026), they stop delaying generic Pomalyst (first quarter of 2026).

[170] Par also sponsored a generic Pomalyst ANDA and did not receive a Revlimid payment. However, Par dropped its patent litigation ten months after Celgene sued and appears to have ceased pursuing a generic Pomalyst product. In August 2022, Par filed for bankruptcy.

1. The Revlimid settlement agreements included output restrictions that kept supply below demand.

434. December 2015, Celgene began constructing the Generic Revlimid Output Restriction by settling ANDA litigation against a collaborative of Natco and subsidiaries of Allergan plc ("Allergan"), the first-filer on four of six strengths. The Natco/Allergan collaborative agreed to a late date for generic entry—quickly fixed on ten years later, January 2026—with Celgene agreeing in the meantime to share with Natco/Allergan some of the profits Celgene would be making from the prolonged period of selling Revlimid in the U.S. The tool to effectuate the profit share was a market-sharing arrangement that ensured constrained supply and thus constrained competition for four years, while the Natco/Allergan collaborative's share of monopoly profits increased in each of the four years, starting with a "mid-single-digit percentage."[171] Because the Natco/Allergan/Teva collaborative (with Teva joining as the marketer, see ¶ 448 & n. 190) receives an "annual quota" of limited product to sell[172], the agreement also functions as an implicit agreement for Celgene to not launch an authorized generic (AG), because doing so would only capture more lucrative brand sales. As of May 2025, Celgene has not launched an AG despite generic "entry" three years prior. Functionally, promising not to launch an AG ("no-AG promise") is a cognizable form of a reverse payment.

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[171] Paul Kleutghen, *Generic Revlimid in Myeloma: Don't Get Too Excited*, HEALTHTREE FOUNDATION, Apr. 10, 2022, https://healthtree.org/myeloma/community/articles/generic-revlimid-in-myeloma--dont-get-too-excited#:~:text=Teva%2FNatco%20will%20have%20little,best%20to%20maximize%20their%20profits.

[172] Teva Pharmaceuticals, Q1 2025 Aide Memoire, available at https://s24.q4cdn.com/720828402/files/doc_financials/2025/q1/Teva-Aide-Memoire-Q1-2025-vF4.pdf (last accessed May 12, 2025) (the agreement "provides a new ***annual quota*** in March of each year," until "2026, at which point Teva expects lenalidomide revenues to decrease substantially").

The no-AG promise restrains competition and allows generic(s) to sell at supracompetitive prices, resulting in excess profits that the generic would otherwise be unable to make.

435. The agreement also contained a most-favored entry clause to coordinate entry dates amongst would-be generics, to deter other generics from litigating Celgene's Revlimid patents and launching at unrestrained volumes, and to provide assurance to the Natco/Allergan collaborative that it would receive the most favorable entry date and retain its lucrative exclusivity period.

436. After Celgene settled with Natco/Allergan, the economic intent and effect of the agreement was clear. In May 2018—i.e., *before any other Revlimid or Pomalyst settlement deals had been reached*—Plaintiff David Mitchell noted the classic output restriction features: "The deal gives Natco no incentive to lower its price . . . because the company can't gain additional market share by undercutting Celgene on price . . . They cut a deal that will keep the price high."[173]

437. Celgene then proceeded to induce settlement with other generic Revlimid companies, including Dr. Reddy's which was the first-filer on two of six strengths of Revlimid, on similar terms to the Natco/Allergan agreement. These later agreements kept the total allocations below total generic demand for the period from 2022 through January 31, 2026. Allocations were also used to induce settlement with, according to public statements and publicly available sales information, Alvogen, Cipla, Apotex, Zydus, Sun, Aurobindo, Mylan, and Hetero.

438. Natco/Allergan/Teva, Dr. Reddy's, Alvogen, Apotex, Aurobindo, Mylan, and Hetero accepted a Revlimid generic "annual quota" of capsules to sell at supracompetitive prices

[173] Alison Kodjak, *How a Drugmaker Gamed The System To Keep Generic Competition Away*, NPR, May 17, 2018, https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away.

until January 31, 2026 and also agreed to wait until the same time (the first quarter of 2026) to launch their generic Pomalyst products. The three Revlimid Generics that did not file a Pomalyst ANDA (Cipla, Zydus, and Sun) nonetheless had developed, and would launch, generic Pomalyst in the rest of the world, demonstrating that they could file a Pomalyst ANDA at any point (and may still).

439. In 2022, after these other Revlimid Generics also settled for small volume-limited entry similar to the agreement with the Natco/Allergan collaborative, observers noted the "'unique' patent settlement where US major Bristol Myers Squibb is 'sharing the pie' of drug Revlimid with Indian generics, including Natco and Dr Reddy's."[174] In April 2022, after an additional nine generics had been induced to join the Generic Revlimid Output Restriction, but after *only* the Natco/Allergan collaboration had actually launched at limited quantities (on March 7, 2022), the intention and effects of the output restriction were clear. As a former pharmaceutical executive who had retired after being diagnosed with multiple myeloma explained:

> Teva/Natco will have little incentive to lower the price of Revlimid to us patients as they will not have to face competition from other generic manufacturers/marketers for some months. That is just pure economics where companies will do their best to maximize their profits. Please be aware that while we (in the US) are used to Revlimid pricing of about $908 per capsule (e.g., as is currently paid by Medicare), its manufacturing cost is about $1.00 for that same capsule . . . the **price differential between the brand and the generic is a mere 9%.**
>
> Even if there will be 6 generic manufacturers/marketers present on the US market by year-end, they will only be allowed a combined total of about 30% market share. **This is simply not competition** that will meaningfully lower the cost/copay of this badly needed medication, not today and not in the next two years. **True competition and meaningful price/copay reductions in the Revlimid /lenalidomide market will not happen until the total supply that can be made**

[174] Rupali Mukherjee, *Unique deal gives desi pharma cos slice of cancer drug's $8bn US pie*, THE TIMES OF INDIA, Mar. 14, 2022, https://timesofindia.indiatimes.com/business/india-business/unique-deal-gives-desi-pharma-cos-slice-of-cancer-drugs-8bn-us-pie/articleshow/90189785.cms

> **available by generic companies will exceed the total demand of the market** (estimated around 2025).[175]

440. Although forbidden from commenting on revenue, volume, and actual prices by the settlement agreements[176], an Aurobindo executive accidentally explained in May 2023 that the scheme eliminated price competition regardless of the number of competitors:

> "this is going to be limited share for multiple players, so we expect the price pricing[] to be stable and **it doesn't matter before Jan 2026 whoever or a number of launches might happen . . . because each player is [] restricted by the percentage of [] share . . . we expect the pricing to be stable up to Jan 2026**. . ."[177]

441. Predictions that the Generic Revlimid Output Restriction would restrain competition and maintain pricing have been confirmed, both directly by executives of the generic companies and by publicly available pricing data. In August 2023, the Aurobindo executive again stated: "**we expect the pricing to be stable** because you know it very well, **it is**

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[175] Paul Kleutghen, *Generic Revlimid in Myeloma: Don't Get Too Excited*, HEALTHTREE FOUNDATION, Apr. 10, 2022, https://healthtree.org/myeloma/community/articles/generic-revlimid-in-myeloma--dont-get-too-excited#:~:text=Teva%2FNatco%20will%20have%20little,best%20to%20maximize%20their%20profits (emphasis added).

[176] *See e.g.*, Transcript, Aurobindo Pharma Q1 FY24 Earnings Conference Call, Aug. 14, 2023, at 12, https://www.aurobindo.com/api/uploads/conferencecalltranscripts/ Aurobindo%20Q1%20FY24%20con%20call%20Transcript.pdf ("we are not supposed to tell what exactly is the volume settlement"); Transcript, Dr. Reddy's Laboratories Lim. Q3 FY23 Earnings Conference Call, Jan. 25, 2023, at 6 https://www.drreddys.com/cms/cms/sites/default/files/2023-01/DrReddys-Earnings-Jan25-2023.pdf ("I cannot share any numbers about the product, sorry"); Transcript, Natco Pharma Lim. Q3 FY '23 Earnings Conference Call, Feb. 10, 2023, at 13, https://www.natcopharma.co.in/wp-content/uploads/2023/02/Nuvama-NatcoPharma-Feb10-2023.pdf (when asked on market pricing, a Natco executive responded, "I can't answer that question, my friend. I'm sorry, I can't answer.").

[177] Transcript, Aurobindo Pharma Q4 FY23 Earnings Conference Call, May 29, 2023, at 12, https://www.aurobindo.com/api/uploads/conferencecalltranscripts/Aurobindo%20Pharma%20Q4%20FY23%20Earnings%20Conference%20Call%20final.pdf (emphasis added).

a limited volume . . . So we expect the pricing to be stable till the end of 2025."[178] The accuracy of those expectations were then confirmed again when a year later in August 2024, he said, "Qualitatively **at this point of time, yes, the pricing remains constant. We don't see any decline** . . . ."[179]

442. During a Teva's earnings calls, analysts regularly referred (uncorrected by Teva executives) to lenalidomide's "**limited competition dynamics**," during the 2022-2026 period, which Teva's executives admitted "there is going to come to a point where this is going to end."[180] The reason for the limited competition was unambiguous, as Teva executives described the market: "**Revlimid is allocated**."[181] As a Dr. Reddy's executive explained, "The volume is impacted primarily by the **type of agreement and less about capturing market share** or anything like that. And so far so good. We are selling the product exactly in accordance to the

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[178] Transcript, Aurobindo Pharma Q1 FY24 Earnings Conference Call, Aug. 14, 2023, at 12, https://www.aurobindo.com/api/uploads/conferencecalltranscripts/Aurobindo%20Q1%20FY24%20con%20call%20Transcript.pdf

[179] Transcript, Aurobindo Pharma Q1 FY2025 Earnings Conference Call, Aug. 12, 2024, at 8, https://www.aurobindo.com/api/uploads/conferencecalltranscripts/Aurobindo%20Q1%20FY25%20Transcript_Final.pdf (emphasis added).

[180] Transcript, Teva Pharmaceuticals Industries, Ltd. Q2 FY24 Earnings Conference Call, Jul. 31, 2024, at 13-14, https://s24.q4cdn.com/720828402/files/doc_financials/2024/q2/CORRECTED-TRANSCRIPT-Teva-Pharmaceutical-Industries-Ltd-TEVA-IL-Q2-2024-Earnings-Call-31-July-2024-8-00-AM-ET.pdf (emphasis added).

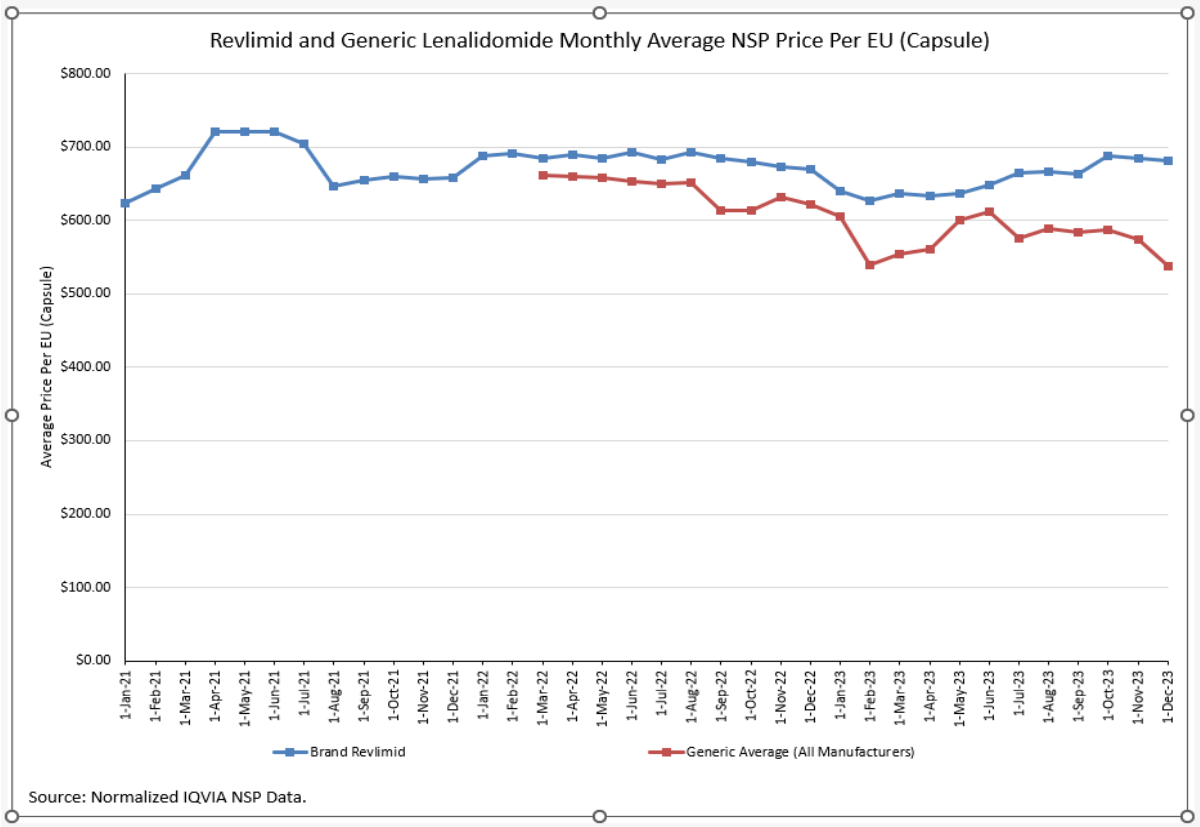
[181] Transcript, Teva Pharmaceuticals Industries, Ltd. Q2 FY24 Earnings Conference Call, Jan. 29, 2025, https://www.fool.com/earnings/call-transcripts/2025/01/29/teva-pharmaceutical-industries-teva-q4-2024-earnin (emphasis added). A Natco executive explained their thoughts in the earnings call following Natco/Teva's 2022 launch, "unless you have something interesting and special or limited competition, it is very difficult to make money." Transcript, Natco Pharma Limited Q1 FY23 Earnings Conference Call, Aug. 10, 2022, at 14, https://www.natcopharma.co.in/wp-content/uploads/2022/08/Edelweiss-NatcoPharma-10Aug-2022.pdf.

contract."[182] As Mylan's CEO explained, generic Revlimid had outsized revenue due to its unique "**profit profile**."[183]

443. Although the price for pharmaceutical drugs generally drops 90% within a year after entry of three to four generics, publicly available pricing data for Revlimid and generic Revlimid confirms what the above executives of generic companies have described – a minimal price discount to brand Revlimid observed at the first generic launch (Natco/Allergan/Teva, March 7, 2022) that has remained largely unaffected by the launch of *nine other generics* (Aurobindo, October 1, 2023).

[182] Transcript, Dr. Reddy's Laboratories Limited's Q1 FY25 Earnings Conference Call, Jul. 27, 2024, at 12, https://www.drreddys.com/cms/cms/sites/default/files/2024-08/DRL_Q1FY25%20Earnings%20Call%20Transcript_27July2024.pdf.

[183] Transcript, Viatris Inc.'s Q4 FY24 Earnings Conference Call, Feb. 27, 2025, https://seekingalpha.com/article/4762846-viatris-inc-vtrs-q4-2024-earnings-call-transcript (emphasis added).


Revlimid and Generic Lenalidomide Monthly Average NSP Price Per EU (Capsule)
$800.00
$700.00
$600.00
$500.00
$400.00
$300.00
$200.00
$100.00
$0.00
Average Price Per EU (Capsule)
1-Jan-21
1-Feb-21
1-Mar-21
1-Apr-21
1-May-21
1-Jun-21
1-Jul-21
1-Aug-21
1-Sep-21
1-Oct-21
1-Nov-21
1-Dec-21
1-Jan-22
1-Feb-22
1-Mar-22
1-Apr-22
1-May-22
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1-Jul-22
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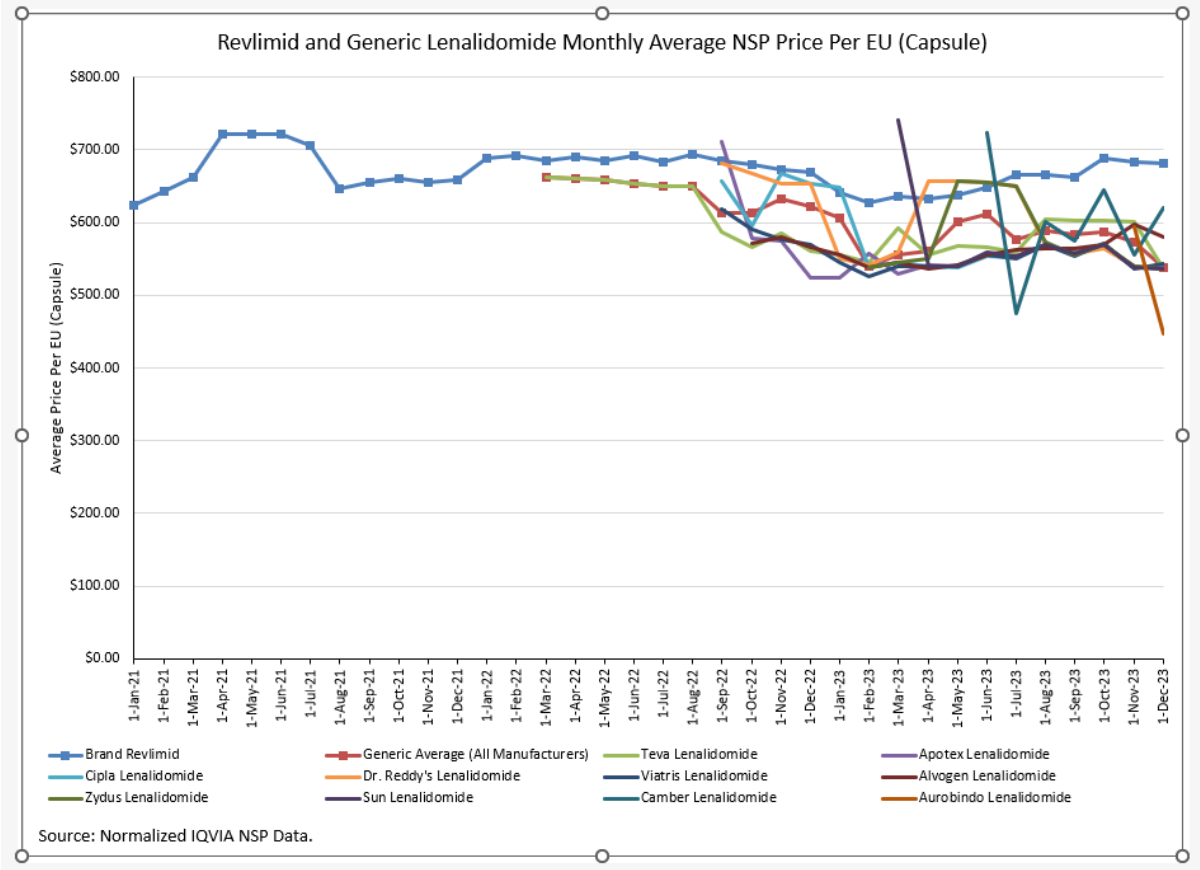
1-Dec-22
1-Jan-23
1-Feb-23
1-Mar-23
1-Apr-23
1-May-23
1-Jun-23
1-Jul-23
1-Aug-23
1-Sep-23
1-Oct-23
1-Nov-23
1-Dec-23
Brand Revlimid
Generic Average (All Manufacturers)
Source: Normalized IQVIA NSP Data.



2. The Federal Trade Commission agrees that settlements for volume-limited generic launches can be reverse payments.

444. On January 15, 2025, the FTC released four reports and an accompanying article authored by the Acting Assistant Director for its Health Care Division, entitled *Reverse Payments: From Cash to Quantity Restrictions and Other Possibilities*.[184] The FTC reports summarize Hatch-Waxman settlement agreements filed with the FTC in 2018-2021 under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"). The reports state FTC's position that agreements that restrict the quantity the settling generic can sell for a period

[184] *See* Brad Albert, Hannah Lamb, *Reverse Payments: From Cash to Quantity Restrictions and Other Possibilities*, FTC, Jan. 15, 2025, https://www.ftc.gov/enforcement/competition-matters/2025/01/reverse-payments-cash-quantity-restrictions-other-possibilities (all four reports can be found linked in this article).

of time like those in the Revlimid settlement agreements can be a form of "possible compensation."[185]

445. As the FTC article accompanying the reports explains, quantity restrictions in Hatch-Waxman settlements "have the potential to alter the competitive dynamics of the market, maintain supracompetitive prices, and allow for the sharing of monopoly profits between the patentee and patent challengers."[186] Where, as in the Revlimid settlement agreements, "the quantity permitted to be sold under the restriction is relatively small, the settling company may have little incentive to compete by lowering price, resulting in supracompetitive prices on products sold by both the brand company and its generic or biosimilar competitor. In some cases, such quantity restrictions may be effectively a de facto market allocation between the patent holder and the patent challengers."[187]

446. That is exactly the case here.

3. Through the Generic Revlimid Output Restriction, Celgene transferred large and unjustified reverse payments to generic Pomalyst ANDA sponsors totaling hundreds of millions of dollars.

447. The eight litigating Pomalyst ANDA sponsors (Natco, Teva, Dr. Reddy's, Mylan, Apotex, Alvogen, Aurobindo, and Hetero) received large and unjustified reverse payments in their generic Revlimid patent settlement agreements.[188] Using publicly available information, the

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[185] *Id.* at, *e.g.*, 2018 Report, at 2 ("[P]ossible compensation include[s] . . . [a]n agreement that restricts the quantity the settling generic can sell for a period of time.").

[186] *Id.*

[187] *Id.*

[188] The only other Pomaylst ANDA filers were Par, a bankrupt pharmaceutical which dropped its ANDA entirely for confidential and unknown reasons, and MSN, which was sued more than five years after the Pomalyst first-filers filed their ANDAs and settled two months later, indicating it posed little litigation danger to Bristol Myers and simply wanted to settle for a late entry date.

key pieces of which were only recently disclosed, plaintiff here alleges the Generic Revlimid Output Restriction transferred hundreds of millions of dollars in excess profits to the eight litigating Pomalyst Generics.[189] The payments below reflect the differential between what these companies would have expected to make under competitive conditions given the circumstances, compared to what they are estimated to have made based on publicly available information. The exact size of the reverse payments (likely larger than here estimated) will be determined through transactional data in discovery and expert analysis.

448. *First-Filer: Natco/Allergan*. The Natco/Allergan collaboration launched its first-filer generic Revlimid product in March 2022. The Natco/Allergan collaboration, which included Teva after Teva's 2016 acquisition of Allergan[190], received a reverse payment that can be estimated at $2.2 billion, with Natco (30% of profits) receiving ~$660 million and Teva (35% of profits) receiving ~$770 million. These estimates are based on the reports of numerous financial analysts tracking Natco revenue (allowing for calculation of Teva revenue) and attending Natco conference calls. These analysts reported that Natco's lenalidomide sales from 2022-March 2024 totaled ~$406-$413.9 million and its April 2024-March 2026 sales projected to total ~$481.5-$591 million.[191] These reports are reliable and available—despite the prohibition

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[189] These estimates use standard methods of calculating reverse payments in scenarios where a brand's settlement agreement restrains price competition, transferring a reverse payment based on the excess profits the restraint allowed the generic to make when compared to standard economic assumptions based on the size of the market, price, number of competitors, etc.

[190] Through a series of corporate transactions in 2015-16, Teva acquired Allergan's generics business in a deal in which Allergan (now AbbVie) retained 50% of Teva's future generic Revlimid revenues and Teva obtained the marketing rights. Thus, revenue is split between Teva (marketer/distributor, 35%), Natco (developer/manufacturer, 30%), and AbbVie (35%).

[191] Analysts in late 2024 and early 2025 estimated between 3,000 and 3,500 crore for FY22-FY24,*see* Nikitha Devi, FY 206 is Here! Why India Follows an April-March Financial Year?, AngelOne, April 1, 2025, https://www.angelone.in/news/fy-2026-is-here-why-india-follows-an-

on commentary on price and volume—because the price has been stable for nearly three years and, as an analyst on a Dr. Reddy's earnings call remarked, "this is there in the public domain in terms of the Rx volume."[192]

449. Analyst reports on Natco's lenalidomide revenue are particularly reliable because of Natco's limited portfolio of generics in the US. Although Natco is prohibited from giving lenalidomide-specific revenue data, analysts can accurately glean the impact of Natco's lenalidomide revenue because Natco has few other US generic drugs, all of which were launched prior to 2022, with no other major launches until 2025.[193] Thus it is unsurprising that analysts can deduce the approximate contribution of generic Revlimid when "Between FY21 and FY24, Natco's revenue . . . grew at . . . 25%, 42%, and 46%, respectively, largely driven by the launch of [generic] Revlimid."[194]

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april-march-financial-year, which converts to roughly $348.9mm - $407mm. Further, analysts projected 3500-5000 crore in the coming two financial years (April 2024-March 2026), converting to $407mm - $581mm. *See* Natco Pharma Ltd. – Quick Insights, Jan. 21, 2025, https://www.way2wealth.com/Reports/RR210120255bdd2.pdf; Nishant Kumar, *Stocks to buy for long term: Pankaj Pandey of ICICI Securities recommends these 5 shares to buy, expects 22-54% upside*, MINT, Nov. 21, 2024, https://www.livemint.com/market/stock-market-news/stocks-to-buy-for-long-term-pankaj-pandey-of-icici-securities-recommends-these-5-shares-to-buy-expects-22-54-upside-11732073816138.html.

[192] Transcript, Dr. Reddy's Laboratories Limited's Q1 FY24 Earnings Conference Call, Jul. 26, 2023, at 8, https://www.drreddys.com/cms/cms/sites/default/files/2023-07/DrReddys-Jul26-2023_v1.pdf.

[193] *See e.g.*, Transcript, Natco Pharma Limited Q1 FY23 Earnings Conference Call, Aug. 10, 2022, at 14, https://www.natcopharma.co.in/wp-content/uploads/2022/08/Edelweiss-NatcoPharma-10Aug-2022.pdf ("I think if we remove Lenalidomide which is the elephant in the room, the other portfolio has been steady, it has not, in fact may be declined slightly, but it has been steady, but we have made up with like launches in the other [rest of world] market, I think that is what has happened"); *id.* at 15 ("Lenalidomide doesn't make much of a difference because of the size of Teva's balance sheet. It makes a lot of difference for us because we are a smaller company").

[194] Natco Pharma Ltd. – Quick Insights Update, Feb. 17, 2025, at 2, https://www.way2wealth.com/reports/RR210120255bdd2.pdf.

450. *Second Wave Revlimid Generics: Mylan, Alvogen, Apotex.* Publicly available and unintentionally disclosed information confirms that Mylan, Alvogen, and Apotex, which all launched six months after the Natco/Allergan collaboration in September 2022 ("Second Wave Generics"), received reverse payments of *at least* $400 million. These numbers were able to be publicly confirmed only when Mylan was forced to disclose (per the disclosure requirements of the Security and Exchange Commission) that the Indian plant that manufactures Mylan's lenalidomide received an FDA warning letter and that it would therefore suffer a shortfall of its expected **$200 million in 2025 alone from lenalidomide revenues.**[195]

451. *First-Filer, Second-Wave: Dr. Reddy's.* While public info establishes that, as a Second Wave Generic, Dr. Reddy's received *at least* a $400 million reverse payment, it almost certainly received more. Dr. Reddy's was a first-filer on two of six Revlimid strengths, was the third to settle, and had a rock solid non-infringement argument (see below ¶¶ 456-58) on all relevant patents that expired after October 2023, meaning it had significant leverage to extract a large

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[195] Viatris Q4 & Full Year 2024 Earnings Presentation, Feb. 27, 2025, at 2 & 29, https://investor.viatris.com/static-files/5c33d741-1505-4446-864d-f0ed3cae2525 (specifically, Mylan disclosed that "Lenalidomide represents ~40% of the total estimated 2025 total revenues impact. . .[with] total estimated financial impact in 2025 of ~$500 million to total revenues" or $200 million); Transcript, Viatris Inc.'s Q4 FY24 Earnings Conference Call, Feb. 27, 2025, https://www.investing.com/news/transcripts/earnings-call-transcript-viatris-inc-q4-2024-misses-eps-estimates-stock-dives-93CH-3896811 ("Lenalidomide, which after discussions with the FDA was not granted an exception, is the largest product impacted and represents approximately 40% of the total revenue impact. . . ."). Using Bristol Myers prices for Revlimid and its publicly disclosed annual revenue, along with its statement that in 2025 "about 70% of the market will be supplied by generics," plaintiff can estimate the relative brand/generic share across the 2022-2026 period. Assuming Mylan's allocation rose roughly in proportion to generic share and its revenue rose accordingly from 2022-2024 to $200 million in 2025, the plaintiff can estimate total Mylan revenue, comparing against standard competitive assumptions. These assumptions would apply to the other Second Wave Generics, who litigated and launched at the same time. As Mylan was the *last* of the Wave 2 Revlimid Generics to settle, it is reasonable to expect that it would have the *least* leverage and would thus that Celgene/Bristol Myers would offer the smallest reverse payment to induce settlement.

reverse payment. As explained below, Celgene has not contested that Dr. Reddy's would have been able to launch at unlimited quantities after an earlier litigation victory by October 2023 at the *latest*. Given its strong leverage, and Celgene's motivation to build the Generic Revlimid Output Restriction (and reap the financial gains of four more years of greater brand sales), Dr. Reddy's likely obtained a reverse payment roughly twice the size of the other First Wave Generics ($800 million), which would still be less than half of the other First-Filer's reverse payment (Natco/Teva/Allergan's approximately $2.2 billion reverse payment).[196] Regardless of the ultimate details, the payment was large and unexplained and was paid to eliminate the risk that Dr. Reddy's would have launched earlier, triggering acceleration clauses in other generics' (Natco/Allergan/Teva and Alvogen) settlement agreements and leading to more and earlier competition.

452. *Third-Wave Revlimid Generics: Aurobindo and Hetero*. Publicly available and unintentionally disclosed information confirms that Aurobindo and Hetero, which were granted generic Revlimid allocations and launched beginning in Spring and October 2023 ("Third Wave Generics"), received reverse payments of at least $160 million.[197] The minimum amount of these reverse payments is confirmable from publicly available information, including Aurobindo's statements about its expected revenue in comparison to the competitive dynamics it would have

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[196] This coheres with analyst estimates in mid-2023 that Dr. Reddy's had been "achieving 6% kind of volume share," in 2023. Transcript, Dr. Reddy's Laboratories, Ltd. Q1 FY24 Earnings Conference Call, Jul. 26, 2023, at 8, https://www.drreddys.com/cms/cms/sites/default/files/2023-07/DrReddys-Jul26-2023_v1.pdf.

[197] As the ninth and tenth generics on the market, it is reasonable to expect that these generics had smaller allocations than Mylan (the seventh generic). *See* Transcript, Aurobindo Pharma Q1 FY24 Earnings Conference Call, Aug. 14, 2023, at 12, https://www.aurobindo.com/api/uploads/conferencecalltranscripts/Aurobindo%20Q1%20FY24%20con%20call%20Transcript.pdf (". . . we are in the third wave. We are expected to be much lower . . .").

faced as the likely *eleventh* generic (10 generics + an AG) product to launch (and admission that "the pricing remains constant").[198] Given that Hetero's competitive posture was similar to Aurobindo's, Hetero likely received a similarly sized, if not bigger (it launched in Spring as the ninth generic), reverse payment.[199]

453. Although the above alleged reverse payments are all large, the publicly available information on the total generic volume and price indicates that the Second and Third Wave Generics in total received far more than what is publicly *confirmable* above. This is because the above alleged reverse payments would only account for roughly $2.874 billion of the conservatively estimated $3.652 billion the Revlimid Generics are estimated to be making in 2025 alone.[200] Thus, while $160 million to Hetero and Aurobindo is publicly confirmable, the likely reverse payments for these two total $219-$256 million.[201]

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[198] An Aurobindo executive implicitly disclosed that it was forecasting Revlimid would provide annual revenue reaching $50-150 million in revenue over the limited competition period. *Id.* at 10. ("So, first thing is, we will treat these as two different things. One is, how do we grow the base business. That is the 500, how we can go to 550 and all, plus Revlimid. Put together, it might be 600-650"). Conservatively estimating $100 million in 2025 (period with the greatest generic market share per Bristol Myers's statements), the reverse payment is at least ~$160 million.

[199] Hetero litigated at the same time as Aurobindo and would have expected to launch with similar numbers of competitors, to gain similar market share at similar prices, and earn roughly similar revenue. As Hetero launched before Aurobindo, its payment would have been more.

[200] One knows this because the volume of the market is growing while the price is constant (~$574 or 84% of the brand price from 2021, when Bristol Myers made $8.695 billion), Bristol Myers itself said that generics will supply 70% of the market in 2025. Thus, even if the price fell from the observed 2024 price of ~$574 to ~$410.40 (60% of brand price from 2021), 70% of the market would still account for $3.652 billion.

[201] These entities would only be expected to be making ~$12 million in 2025 absent the volume limits, and it is not publicly knowable how Celgene/Bristol Myers doled out the remaining allocations that would account for the $778 million in estimated 2025 generic Revlimid revenue between the eight Second and Third Wave Filers other than Mylan. To illustrate, if the allocations were divided evenly, Aurobindo and Hetero's reverse payment would be at least $256 million. If the Second Wave Filers' allocation was twice the size of the Third Wave, Aurobindo and Hetero's reverse payment would be $219 million.

4. The Reverse Payments transferred via the Revlimid monopoly profit share were and continue to be unlawful.

454. Celgene serially created the Generic Revlimid Output Restriction as part of a monopolistic scheme to restrain competition. The Output Restrictions were not the result of an arms' length negotiation to settle a good faith dispute regarding the patents, but rather a means to buy off competition sharing the monopoly profits that resulted from a restricted market.

455. *Predicted and Predictable*. As above, the creation of the Generic Revlimid Output Restriction was predictable and was in fact predicted in 2018 prior to any other settlement. The intention to create the output restriction and restrain price competition was clear from this first settlement agreement because without assurance from the terms of the settlement agreement that prices would remain restrained under an output restriction, it would have been irrational for the Natco/Allergan collaborative to *voluntarily* sell only a single-digit volume of sales during its 180-day exclusivity period. As described above, a first-filer typically makes 80% of their profits during the 180-day exclusivity period because it can quickly gain 39% market share (with an AG). To completely surrender the ability to maximize the first-filer exclusivity—the cornerstone of the Hatch-Waxman regime—indicates the Natco/Allergan collaborative understood they could make, as publicly available information *confirms they have made*, vastly more money during a longer period of time by agreeing to delay competition and instead receive allocations through the Generic Revlimid Output Restriction.

456. *Celgene's Revlimid patents do not explain nor justify the Revlimid settlements*. Under *FTC v. Actavis*, [202] the massive size of these reverse payments serves as a proxy for the weakness of

[202] 570 U.S. 136, 158 (2013) ("In a word, the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself.").

Celgene's Revlimid patents because it would otherwise be irrational for Celgene to be freely giving away billions of dollars in brand sales from 2022-2026.

457. Public information about the Revlimid patents further corroborates that the reverse payments in the hundreds of millions of dollars were unjustified and cannot be explained by anything other than a pay-for-delay *quid pro quo*. After October 2023, Celgene's only remaining relevant patents were crystal form patents[203] covering crystal forms of the drug product that would not have served as an impediment to early generic competition.[204] For example, Natco invented a novel and noninfringing crystal form (Form I).[205] Confident in its position, Natco made a 2014 revision to its ANDA product specification that meant that its ANDA did not infringe Celgene's key 2027-expiring crystal form patent (the '800 patent) as a matter of law.[206] Celgene's crystal form patent position as to Dr. Reddy's was even weaker, as Dr. Reddy's had invented an amorphous (i.e., not a crystal) product form that did not infringe the Crystal Patent (the '800) and over which Dr. Reddy's was virtually certain to prevail.[207]

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[203] Celgene's only remaining other type of patent was a method of treatment pertaining to a use that had been carve out by virtually all of the Revlimid Generics according to the Final Approval letters available on the FDA website, as therefore would not have been an impediment to generic launch.

[204] *See* Appendix A (detailing the Revlimid patents and Natco litigation).

[205] Not to be confused with Hetero's pomalidomide Form I, discussed above.

[206] *E.g.*, *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249-50 (Fed. Cir. 2000). *Compare* Redacted Opposition to Motion to Dismiss, *In re Revlimid Purchaser Antitrust Litig.*, No. 19-cv-7532 (D.N.J. Mar. 4, 2025), ECF No. 557 at 10-12 & n.8, *with* Redacted Reply in Support of Motion to Dismiss, ECF No. 559 (does not contest patent merit allegations).

[207] *Id.* All the generic companies, furthermore, possessed strong invalidity arguments, Dr. Reddy's had strong invalidity defenses that the claims of the '800 patent were invalid as indefinite, lacking adequate written description, and not enabled as construed under the Court's construction of the meaning of the disputed term "hemihydrate."

458. Celgene has not contested these noninfringement allegations, nor that, absent their illegal conduct, Celgene's patents could not have prevented at least Dr. Reddy's from launching (in unlimited quantities, without a license) by October 2023. And since Natco and Alvogen settled for acceleration clauses prior to the Dr. Reddy's settlement, at the bare minimum (uncontested), these three generics would have launched and driven down prices starting in October 2023 at the very latest.[208]

5. The Revlimid monopoly profit share aligned the generic manufacturers' interests with Celgene through Jan. 31, 2026, when the Revlimid caps end and unfettered generic Revlimid and generic Pomalyst competition will finally begin.

459. Through the creation of the Generic Revlimid Output Restriction, Celgene aligned the economic incentives of the Revlimid Generics with Celgene's own brand incentives, turning all the generics into *de facto* co-brand drugmakers rather than competitors.

460. *FTC v. Actavis* prohibits the sharing of monopoly profits to induce delay. Here, Celgene induced delay by sharing both monopoly profits *and* monopoly power (that often accompanies powerful patents) via the creation of the Generic Revlimid Output Restriction that allowed 10-11 generics to price generic Revlimid between $500-$650 a pill instead of, at most, $50. As the Supreme Court said in *FTC v. Actavis*:

> But settlement on the terms said by the FTC to be at issue here—payment in return for staying out of the market—***simply keeps prices at patentee-set levels***, potentially producing the full patent-related $500 million monopoly return while dividing that return between the challenged patentee and the patent challenger. The patentee and the challenger gain; the consumer loses. Indeed, there are indications that patentees sometimes pay a generic challenger a sum

[208] *See* Redacted Opposition to Motion to Dismiss, No. 19-cv-7532, ECF No. 557 at 37 (settlements had acceleration clauses). Dr. Reddy's settled in 2020, after the 2015 Natco settlement and 2019 Alvogen settlement.

> even larger than what the generic would gain in profits if it won the paragraph IV litigation and entered the market.[209]

461. Through the Generic Revlimid Output Restriction, Mylan (and the other generics) were functionally sharing in the power of Celgene's Revlimid patents. Thus, although from 2022-2026 there were 10-11 generic products nominally "on the market," analysts constantly noted that the generics were functionally brand companies with the exclusivity power that comes with patents. This is because each received a fixed "quota" less than market demand that would thereby keep price competition restrained.

462. On Zydus's[210] February 2025 earnings call a participant stated (unrebutted by Zydus) that "Going into FY26, by Q4 [on the Indian fiscal calendar, Jan-Mar. 31, 2026], the **exclusivity of the generic settlers** will be over."[211] Articles stated that Natco faces "loss of exclusivity in g[eneric] Revlimid in FY27,"[212] and that Dr. Reddy's "**g[eneric] Revlimid is nearing the cliff**."[213]

463. That Revlimid agreements rendered the Revlimid Generics functionally as co-patentees, which underscores that the output restriction aligned Celgene's interest in avoiding all

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[209] *FTC v. Actavis*, 570 U.S. 136, 154 (2013) (emphasis added).

[210] Zydus is a Revlimid Generic that, although it does not have a Pomalyst ANDA in the US, has developed a pomalidomide product which it has launched in numerous countries worldwide, e.g., in southeast Asia in 2022. *Lotus Reports Its Best Quarter Ever With the Biggest Launch in Its History*, Lotus Pharmaceuticals, Nov. 10, 2022, https://www.lotuspharm.com/newsroom/lotus-reports-its-best-quarter-ever-with-the-biggest.

[211] Transcript, Zydus Lifesciences, Ltd. Q3 FY25 Post Results Earnings Call, Feb. 5, 2025, at 15, https://zyduslife.com/investor/admin/uploads/16/0/Earnings-call-transcript-05-Feb-25.pdf (emphasis added).

[212] Natco Pharma Ltd. – Quick Insights, Jan. 21, 2025, at 7, https://www.way2wealth.com/Reports/RR210120255bdd2.pdf.

[213] Dr. Reddy's Labs – Result Update, NUVAMA INSTITUTIONAL EQUITIES, Jan. 23, 2025, at 1, https://bsmedia.business-standard.com/_media/bs/data/market-reports/equity-brokertips/2025-01/17377083580.22898500.pdf (emphasis added).

competitive threats to brand Revlimid and allocated generic Revlimid, including generic Pomalyst.

AA. Competitively-priced generic Pomalyst threatened brand and Generic Revlimid Output Restriction profits from 2022 through January 31, 2026.

1. Revlimid and Pomalyst treat overlapping conditions.

464. Revlimid and Pomalyst both treat multiple myeloma.

465. There is no cure for multiple myeloma; patients diagnosed with the disease will almost certainly die from it. In the best-case scenarios, diagnosed patients delay death while going through numerous rounds of treatment, marked by varying periods of remission (often while receiving "maintenance" level treatments) before relapse, after which patients often if not always become refractory to prior treatments.

466. The total number of patients in the United States is probably around 140,000 to 160,000, with many of them being relapsed and refractory. Almost everyone progresses beyond their initial therapy and becomes relapsed and refractory, with that population slowly growing. Most of them are in the earlier relapses because the average number of therapy lines that a patient with myeloma gets in the United States is around 3 to 4.[214]

467. Revlimid was first approved for treatment of relapsed or refractory multiple myeloma in 2006. Revlimid was then also approved for use as a first-line treatment option in 2015 as part of receiving approval for a label to treat multiple myeloma (i.e. at any point) with dexamethasone.

468. Pomalyst, in combination with dexamethasone, is indicated for the treatment of patients who have received at least two prior therapies including lenalidomide and a proteasome

[214] IMiDs in Relapsed/Refractory Multiple Myeloma – RRMM: An Overview, AJMC, Jun. 7, 2022, https://www.ajmc.com/view/rrmm-an-overview.

inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy. Even with this narrower indication, Pomalyst is still indicated for use in myriad circumstances. Numerous studies have shown the safety and efficacy of these regimens.[215] Beyond the indication, doctors often prescribe Pomalyst as a second-line treatment, which has been demonstrated to be effective in numerous studies.[216]

469. Although exact numbers of use per "line" (itself an imprecise generalization of treatment patterns) is difficult to track, studies have shown that the use of Pomalyst combinations in second line treatments grew substantially from its approval in 2013 through settlements in the 2019-2021 period. Nonetheless, treatment with Revlimid remained and remains a large proportion of second line treatments.

470. Pomalyst, like Revlimid, has also been studied and been found to be safe and effective in other contexts for treating multiple myeloma, including maintenance therapy.[217] Maintenance therapy is a lucrative treatment option for Celgene. Although the patient is in

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[215] *Multinational Clinical Study Comparing Isatuximab, Pomalidomide, and Dexamethasone to Pomalidomide and Dexamethasone in Refractory or Relapsed and Refractory Multiple Myeloma Patients (ICARIA-MM)*, SANOFI, https://clinicaltrials.gov/study/NCT02990338 (in combination with Isatuximab and dexamethasone); Paul G. Richardson, Fredrik Schjesvold, Katja Weisel, et al., *Pomalidomide, bortezomib, and dexamethasone at first relapse in lenalidomide-pretreated myeloma: A subanalysis of OPTIMISMM by clinical characteristics*, Eur J Haematol. 2021 Sep 22;108(1):73–83, https://pmc.ncbi.nlm.nih.gov/articles/PMC9293199/ (in combination with bortezomib and dexamethasone); https://ascopubs.org/doi/full/10.1200/JCO.2017.76.1742 (in combination with dexamethasone).

[216] IMiDs in Relapsed/Refractory Multiple Myeloma: Preferred IMiDs Regimens Based on Line of Therapy, June 14, 2022, https://www.ajmc.com/view/preferred-imids-regimens-based-on-line-of-therapy; Mark, Tomer, *Real-World Outcomes of Pomalidomide Therapy after Lenalidomide Induction in Relapsed/Refractory Multiple Myeloma*, FUTURE ONCOLOGY, Nov. 17, 2021, https://doi.org/10.2217/fon-2021-1176 (safe and effective).

[217] Gardaret et al., *Phase II Study of the Combination of Pomalidomide with Dexamethasone As Maintenance Therapy after First Relapse Treatment with PCD Followed or Not By Autologous Stem Cell Transplant in Multiple Myeloma Patients*, Blood 2021, Vol. 138, Supp. 1, p. 2753, available at https://www.sciencedirect.com/science/article/pii/S0006497121046966.

remission for a period of time that can stretch to years (often one to four years, or 12-48 monthly cycles), the iMiD (Revlimid or Pomalyst) is continuously administered. Pomalyst has been found to be comparably effective in the maintenance context as Revlimid: the median number of cycles (i.e., length of time in which maintenance was effective and tolerated) "was 26 with 25% of patients receiving less than 15 cycles and 25% more than 48 cycles, which is similar to what can be expected using lenalidomide maintenance."[218]

471. However, though studies have shown pomalidomide is safe and effective for maintenance, doctors and clinicians have noted that "**[i]n contrast to lenalidomide, pomalidomide was never strategically developed as a maintenance drug**,"[219] and thus has seen only moderate uptake for this use, including because it is more expensive than Revlimid.

472. In sum, though Celgene's business strategy has been to only pursue Pomalyst indications that would render Pomalyst a complement rather than a substitute for Revlimid, the indication itself is broad enough to be substitutable as a practical matter in a variety of contexts, and real-world use shows that Pomalyst is in fact a therapeutic substitute for Revlimid in many contexts. For example, only Pomalyst is strong enough to use after patients have become refractory to Revlimid, but Pomalyst is also safe enough to nonetheless use earlier than the indications Celgene has pursued.

473. The fact that Celgene did not pursue indications for which Pomalyst was clearly safe and effective, including second-line and maintenance therapy, and instead reserved those indications for Revlimid, bolsters the plaintiff's

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[218] Gardaret et al., *Pomalidomide and dexamethasone until progression after first salvage therapy in multiple myeloma*, BRITISH JOURNAL OF HAEMATOLOGY, Mar. 27, 2023, https://onlinelibrary.wiley.com/doi/10.1111/bjh.18772.

[219] *Id.* (emphasis added).

474. allegations that Celgene knew that Pomalyst was a competitive threat to Revlimid.

2. Generic Pomalyst would have been a substantially cheaper substitute than either brand or allocated Generic Revlimid for overlapping uses.

475. To protect its (earlier built) Revlimid empire from erosion and price competition from its therapeutically overlapping drug Pomalyst, Celgene artificially prices Pomalyst higher than Revlimid. While pomalidomide active pharmaceutical ingredient (API, the raw material) is priced slightly higher than lenalidomide API, the recommended starting dose for Pomalyst is 4mg compared to 25mg for Revlimid, thus requiring multiple times more raw material, meaning Revlimid actually costs more to make.[220] Despite Pomalyst being cheaper to make, Celgene prices Pomalyst *28% higher* than Revlimid: for a 21-day supply, Celgene prices Pomalyst at $25,034 compared to $19,555 for Revlimid.[221] Nor do R&D costs explain the higher Pomalyst price, because Pomalyst was invented before Revlimid (by someone else) and Celgene has only sought a single indication for Pomalyst (requiring costly studies). And, either way, as above, Revlimid reportedly only costs approximately $1.00 per capsule to make.[222]

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[220] Pomalyst comes in 1, 2, 3, and 4mg capsules, whereas Revlimid comes in 2.5, 5, 10, 15, 20, and 25mg administered in the exact same dosing schedule. Both Revlimid and Pomalyst are sold in either 21- or 28-day packs.

[221] E.g., *compare* https://www.drugs.com/price-guide/revlimid, *with* https://www.drugs.com/price-guide/pomalyst.

[222] Paul Kleutghen, *Generic Revlimid in Myeloma: Don't Get Too Excited*, HEALTHTREE FOUNDATION, Apr. 10, 2022, https://healthtree.org/myeloma/community/articles/generic-revlimid-in-myeloma--dont-get-too-excited#:~:text=Teva%2FNatco%20will%20have%20little,best%20to%20maximize%20their%20profits.

476. That Celgene already has attempted to insulate Revlimid from competition from Pomalyst by artificially pricing Pomalyst higher illustrates and underscores that Celgene is aware that cheaper pomalidomide would be a competitive threat to Revlimid.

477. Celgene and the Revlimid/Pomalyst Generics would be right to view competitively-priced generic Pomalyst as a threat to a significant portion of Revlimid sales. Based on extensive literature and FTC studies, if anywhere from four to eight Pomalyst Generics entered prior to Jan. 31, 2026, prices for pomalidomide would drop at least 85% within a year. This means the cost of a 21-day supply of pomalidomide would decline from a wholesale acquisition cost (WAC) of $25,034 (brand) to at least $3,755 (generic), saving patients and other payors roughly $255,348 per patient/per year.

478. Without the agreements to delay a generic Pomalyst, and assuming earlier competition, Pomalyst would have fast become approximately *19% the price of Revlimid*.

479. Generic Pomalyst also would have been significantly less expensive than the allocated generic Revlimid being sold through the Generic Revlimid Output Restriction, which is now priced at a WAC of $15,118 per month (21-day supply). Thus, if a generic Pomalyst had not been delayed past January 31, 2026 and the pendency of the Generic Revlimid Output Restriction, ***generic Pomalyst would have been ~75% cheaper than allocated generic Revlimid***. For patients on, for instance, multiple years of maintenance therapy with an iMiD, generic Pomalyst would have been an option that offered staggering savings.

3. Generic Pomalyst would have also been more attractive because it would have been widely available, whereas allocated generic Revlimid is subject to intentionally created shortages.

480. Beyond being approximately 75% less expensive than allocated generic Revlimid, the lack of availability of allocated generic Revlimid would have driven large portions of the lenalidomide market from brand and allocated generic Revlimid to generic Pomalyst. As above,

the purpose and effect of the Generic Revlimid Output Restriction was to ensure significant shortages of generic Revlimid in the market and thereby to foster high prices and profits for both Celgene and the Revlimid Generics.

481. For patients, drug shortages on cancer drugs are potentially lethal and for doctors, hospitals, payors, the FDA, and the specialty pharmacies and distributors, drug shortages on cancer drugs are also, of course, a huge problem. Pharmaceutical shortages have severe economic and clinical impacts on those purchasing and relying on the affected medication.

482. Most alarmingly, shortages risk patient safety by increasing the risk of medication errors or delaying effective treatment. Hospital pharmacies prefer to purchase a single version of a medication from a single manufacturer.[223] Thus, the ability to purchase significant amounts of a single version of generic Pomalyst would have been attractive in comparison to sparsely available allocated Revlimid products, likely from different manufacturers.

483. In sum, both the general availability as well as the approximately 75% lower price of generic Pomalyst would have been driven large portions of the market-wide lenalidomide volumes to generic Pomalyst. Thus, generic Pomalyst was and continues to be a threat to brand and allocated generic Revlimid sales prior to January 31, 2026.

[223] Erin R. Fox et al., Drug Shortages: A Complex Health Care Crisis, 89 MAYO CLINIC PROC. 361, 365 (2014).

BB. Revlimid First-Filers: Linked Settlements ensured delayed generic Pomalyst.

1. The Natco/Teva/Allergan Revlimid 2015 settlement and the September 2020 Revlimid Dr. Reddy's settlement agreements ensured that Natco/Teva, and Dr. Reddy's would delay the launch of their pomalidomide product until at least Jan. 31, 2026, because launching pomalidomide beforehand would have severely undercut their massive generic Revlimid cash flows

484. The Revlimid Generic Output Restriction functionally created a ***promise of future cash flows*** that would vest from 2022 to January 31, 2026, with the structure of the Revlimid agreements creating a *de facto* agreement to protect those future cash flows.

485. The Generic Revlimid Output Restriction disincentivized the Revlimid Generics from launching generic Pomalyst prior to January 31, 2026. Any increase in revenue from earlier generic Pomalyst sales would have been offset by significantly more lost revenue from decreased allocated generic Revlimid sales and/or prices. The Revlimid generics currently are making hundreds of millions of dollars in allocated generic Revlimid sales at prices significantly higher (~10x) than could be sold for generic Pomalyst. Whereas, as above, four to eight generics launching generic Pomalyst would have expected to only make only $19.6 million over six months.

486. The structure of the future cash flows further disincentivized generic Pomalyst entry prior to January 31, 2026. Celgene structured the settlements to grant small allocations in 2022, gradually increasing each year through January 31, 2026. The anticipated and observed "stable" price means the participating generics would obtain the most revenue in 2025, before unlimited competition begins and revenues drop.[224]

[224] *See e.g.*, Teva Pharmaceuticals, Q1 2025 Aide Memoire, available at https://s24.q4cdn.com/720828402/files/doc_financials/2025/q1/Teva-Aide-Memoire-Q1-2025-vF4.pdf (Teva provides guidance that "For 2025, the agreements with the settling generics

487. Per estimates based on publicly available information (including Celgene's guidance that generic Revlimid market share would be 70% in 2025, estimates of Natco's past and projected revenue, and Dr. Reddy's first-filer status and strong patent position), the settlements were structured so that Natco, Teva, and Dr. Reddy's would make an estimated ***40% of their 2022-2026 Output Restriction revenue in 2025 alone***. Thus, the incentive to avoid generic Pomalyst was strongest in the period (March 2025 – January 31, 2026) immediately prior to the launch of generic Pomalyst (first quarter of 2026).

488. As Natco, Teva, and Dr. Reddy's (as well as Allergan) received promises of the largest future cash flows, the Revlimid agreements created the strongest disincentives for these entities – they had the most to lose by generic Pomalyst competition arriving prior to January 31, 2026. Without delaying their generic Pomalyst launches until after January 31, 2026, Natco, Teva, and Dr. Reddy's would have threatened hundreds of millions of dollars in generic Revlimid cash flows.

489. Because of this progressively increasing structure, the Generic Revlimid Output Restriction functioned as both a payment vehicle and an *enforcement mechanism*, given the payment would be continuously transferred from 2022-2026.

490. *First*, Natco, Teva, and Dr. Reddy's would lose enormous amounts of allocated generic Revlimid profits if they exceeded their allocations and triggered unlimited competition (i.e., traditional enforcement mechanism for an output restriction).

491. *Second*, Natco, Teva, and Dr. Reddy's would lose enormous amounts of allocated generic Revlimid profits if they launched generic Pomalyst products prior to January 31, 2026.

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companies provide for increased volume / market share for the generics, including new entrant(s).").

2. The Pomalyst agreements delaying generic Pomalyst competition until the first quarter of 2026 were not driven by the substantive merits of the parties' patent positions, but rather were dictated by the incentives established in the Generic Revlimid Output Restriction, delaying generic Pomalyst entry from 2020 until 2026.

492. With the 2015 and 2020 Revlimid deals with the Revlimid first-filers, Celgene bought and secured generic Pomalyst delay through the terms of the Generic Revlimid Output Restriction (January 31, 2026).

493. Upon the expiration of the Generic Revlimid Output Restriction, the incentives for the Revlimid Generics to delay launching a generic Pomalyst expire as well. As above, the generics and Celgene expect price and revenue for lenalidomide to drop precipitously and the generic Pomalyst makers will no longer have shared incentives with Celgene to delay generic Pomalyst. Instead, after the expiration of the Generic Revlimid Output Restriction on January 31, 2026, the Pomalyst Generics are incentivized to come to market as soon as possible.

494. These specific sets of incentives—established in the Revlimid agreements—dictated the litigation and settlement behaviors of Natco, Teva, and Dr. Reddy's in their Pomalyst patent litigations. While Celgene preferred to push out generic entry for Pomalyst as much as possible, Natco, Teva, and Dr. Reddy's were incentivized to litigate for an entry date as close to February 1, 2026 as possible, but no sooner.

495. In addition to the extensive allegations above outlining the weakness of Celgene's Pomalyst patents, *see* Sections V.B–H, V.M–N, V.T; CW FAC Sections V.B–H, V.M–N, V.T., additional factors further bolster the plaintiff's allegations that Celgene's settlements in Revlimid, including the reverse payments, induced delay in generic Pomalyst launch that can neither be explained nor justified by the Pomalyst patents.

496. *First*, that the agreed to generic launch dates in the Pomalyst agreements are slated for after the termination of the Generic Revlimid Output Restriction and were never

accelerated to a point during the Generic Revlimid Output Restriction (i.e., agreed delay by all the Revlimid Generics with Pomalyst ANDAs) underscores that the settlements were not a reflection of the relative merits of the parties' patent positions. The Revlimid Generics not moving to encroach on the allocated Generic Revlimid cash flows shows there's an interest in preserving a brand and generic Revlimid market through January 31, 2026 that is free of low-priced generic Pomalyst.

497. In other words, the moment the Pomalyst Generics **stop getting paid** (January 31, 2026), they **immediately stop delaying generic Pomalyst** competition and instead immediately launch competing generic Pomalyst products.

498. But for the payments transferred by the Generic Revlimid Output Restriction, generic Pomalyst would have launched far earlier.

CC. Revlimid Later Filers: Similar Incentives, Concurrent Revlimid/Pomalyst Settlements.

499. As above, the Revlimid deals with the Pomalyst ANDA sponsors Alvogen, Apotex, Mylan, Aurobindo, and Hetero transferred large and unexplained reverse payments valued in the hundreds of millions of dollars.

500. As with the Natco, Teva, and Dr. Reddy's Revlimid and Pomalyst deals, Celgene's deals on Revlimid and Pomalyst were linked because the Revlimid agreements similarly ensured that each would delay its Pomalyst launch beyond the operating period of the Generic Revlimid Output Restriction (January 31, 2026) because the output restriction operated both as payment and enforcement mechanism to shield Revlimid and allocated generic Revlimid from competitive pressures, including those posed by generic Pomalyst.

501. The linked nature of these Revlimid and Pomalyst deals is further corroborated by the fact that they were concurrently negotiated and executed. This is corroborated by the fact that each Pomalyst deal was announced within roughly a month or less of each Revlimid deal.

The Revlimid deals had been negotiated for 1-3 years before execution for these generics, with mediations taking place in 2019, meaning any lag in time between the announcement of a Revlimid and Pomalyst deal is inconsequential in comparison. The close-in-time announcements of these deals indicates that they were negotiated and agreement was reached concurrently on the material commercial terms of each deal (for Revlimid, volume amount and time periods, for Pomalyst, launch date).

502. Furthermore, on information and belief, including the complexity of the settlement agreements themselves, agreement on Revlimid volume amounts and time periods and Pomalyst launch dates were reached prior to actually executing the two settlement deals in separate written documents.

503. To illustrate, the complete agreements for each (confidential) Revlimid settlement would involve the calculation of volume, timing and amount of licensed periods across four separate licensed periods (for the license agreement), and the mechanisms, liability, consideration, and insurance (for the REMS agreement).

504. It would have been irrational for the parties to go through the complicated and extensive process of negotiating and developing a REMS agreement (implicating the need to secure regulatory approval of amendments to the REMS program) of either Revlimid or Pomalyst settlements prior to reaching agreement on the payment terms in Revlimid.

505. Thus, on information and belief, agreement on the material commercial terms of each linked Pomalyst and Revlimid deals for these Revlimid Later Filers was likely reached long before either of the deals was announced.

506. Furthermore, since the *quid* (payment in the Revlimid litigation) also served as a mechanism for ensuring the *quo* (delay in generic Pomalyst), the settlements did not need to be executed on the same day. In other words, agreement for payment and delay in Revlimid made

payment self-executing for the agreement on delay in Pomalyst. This is evident from the fact that all of the Revlimid deals were struck *prior* to execution of the Pomalyst deals,[225] even though all but the Natco/Allergan and Dr. Reddy's litigations were filed earlier in Pomalyst. As above, this is especially true for the generics receiving the largest reverse payments (Natco, Teva, and Dr. Reddy's).

507. Further details corroborate the linked nature of the Revlimid Later Filers' Revlimid and Pomalyst agreements.

508. *Complete overlap of identities*. Every Pomalyst ANDA sponsor that litigated received a reverse payment in the form of supracompetitive profits from lenalidomide sales.[226] Conversely, every Revlimid ANDA sponsor that also developed a Pomalyst product (including, like Zydus, Cipla, and Sun[227] for launch in the rest of world, thereby demonstrating the ability to file an ANDA) received a reverse payment.

509. *Overlapping subject matter in Revlimid and Pomaylst settlements*. The negotiation of settlements for generic Revlimid and Pomalyst involved overlapping subject matter because both involved negotiation of access, participation, and costs related to access to the same shared REMS system that covered distribution of both drugs.

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[225] While the Hetero Pomalyst deal was *announced* one month prior to the Revlimid deal, on information and belief, the actual agreement was reached prior to the execution and announcement of either.

[226] Par also sponsored a generic Pomalyst ANDA and did not receive a Revlimid payment. Par dropped its patent litigation ten months after Celgene sued. Plaintiff's lack public information regarding Par's decision to change its business strategy but note that Par filed for bankruptcy in 2022.

[227] *See e.g.*, https://www.cipla.com/sites/default/files/Annual-Report-2023-24-%28Double%20page%29.pdf (Cipla in South Africa); https://www.lotuspharm.com/newsroom/1q25-earnings-en (Lotus/Zydus in UK); https://www.indiamart.com/proddetail/pomalex-1-mg-capsules-2853113912088.html (Sun Pharma in India, sold as "Pomalex").

510. *Negotiated and agreed to concurrently*. The linked Revlimid and Pomalyst deals were concurrently negotiated and agreement on the material terms were reached concurrently. These settlements were announced close in time.

ANDA filer(s)	Date Revlimid settlement disclosed to the public	Date Pomalyst consent judgment filed with the court	Length of Revlimid Negotiation from First Publicly Known Mediation	Days Between Settlement Announcements
Alvogen	March 29, 2019	May 9, 2019	31 days (2/26/19)	41 days
Apotex	March 9, 2021	April 19, 2021	680 days (April 2019)	41 days
Aurobindo	July 16, 2021	July 16, 2021	(no mediation information available)	0 days
Hetero	September 24, 2021	August 18, 2021	774 days (6/13/19)	37 days
Mylan	July 21, 2021	N/A – November 2021 is estimated settlement date.	(no mediation information available)	103 days

511. However, even the short length of time between *announcements* of the deals likely overstates the length of time (if any) between when the material terms of the deals (pay in Revlimid, delay in Pomalyst) *were agreed to*. For instance, Hetero and Celgene filed a consent judgment in Revlimid on August 18, 2025. While Hetero and Celgene did not do the same in Pomalyst until September 24, 2021, they held a call with the court on *August 17*, and the Court adjourned upcoming deadlines by three-and-a-half months, likely indicating the parties told the

Court they were in the process of buttoning up a settlement agreement they had already reached agreement on the material terms of.[228]

512. As above, and for the same reasons that the Pomalyst settlements with Natco, Teva, and Dr. Reddy's did not reflect a compromise on the merits of the parties' substantive patent positions (the weakness of the patents which this complaint extensively analyzes). Rather, the settlements with Alvogen, Apotex, Mylan, Aurobindo, and Hetero were indicative of payment rather than an arms-length transaction.

DD. Generic competition will not begin until early 2026, causing Cigna to suffer substantial overcharges on its purchases of Pomalyst.

513. The scheme to extend and maintain a monopoly in the market for Pomalyst and its generic equivalents will prevent generic competition for Pomalyst until 2026. As a result, the plaintiff will be and has been forced to purchase brand Pomalyst at supra-competitive prices through at least that time.

514. Shortly after announcing the settlements, Bristol Myers acknowledged that it was able to achieve a longer delay in generic entry than previously expected. In its quarterly report for the first quarter of 2022, Bristol Myer reported: "Amortization of acquired intangible assets decreased by $96 million in the first quarter of 2022, due to a longer than previously expected market exclusivity period for Pomalyst." In other words, Bristol Myers reported that during the quarter that it announced all Pomalyst patent litigation had been settled, Bristol Myer's expectations regarding its exclusivity period for Pomalyst had changed, because it now expected its exclusivity period to last longer than previously expected, further indicating that the

[228] *Compare Celgene Corp. v. Hetero Labs Ltd. et al.*, No. 2:20-cv-14389 ECF No. 13, at 10 (D.N.J. Jan. 8, 2021), *with* ECF No. 49 (D.N.J. Aug. 16-17).

settlement agreements provide for generic delay period that exceeds what one would have expected based on the patents alone.

515. Absent Celgene's anticompetitive conduct, generic Pomalyst would have been available years ago, on a date to be determined during discovery and as early as October 30, 2020 (when Natco/Breckenridge received final approval).

516. Absent the Pomalyst agreements, under competitive conditions, a reasonable generic company in the positions of the generic companies would have (i) launched generic Pomalyst after prevailing at trial, (ii) launched at risk at some point after obtaining final approval, or (iii) entered into an arm's length, payment-free agreement that provides for unrestricted sales and/or an earlier, risk-adjusted, agreed entry date. Absent the anticompetitive conduct, reasonable generics, not seeking to protect unlawfully obtained supra-competitively priced sales, would have launched as early as October 30, 2020.

517. A 2010 study by the FTC found that on average, within a year of generic entry, generics had captured 90% of corresponding brand sales and (with multiple generics on the market) prices had dropped 85%, findings confirmed by later studies. Given that there were multiple generic filers, it is likely that additional generics would have entered subsequent to Natco/Breckenridge, driving down prices in accord with industry experience.[229] Thus, plaintiff will suffer substantial damages in overcharges on its Pomalyst purchases through at least early 2026.

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[229] *See* R. Conrad and R. Lutter, *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices*, FDA: Generic Competition and Drug Prices (Dec. 2019), available at https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices (last accessed June 20, 2025).

VI. MARKET POWER AND RELEVANT MARKET

518. The relevant product market is brand Pomalyst and its AB-rated generic equivalents. Since 2013, Celgene has possessed monopoly power in the United States with respect to this market by virtue of its 100% market share.

519. In the pharmaceutical marketplace, there is a disconnect between product selection and payment. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Pomalyst, to patients without a prescription. Patients must obtain prescriptions from their physicians. However, a patient's physician has no role in the purchase of the prescription medication. The patient's doctor chooses which product the patient will buy, while the patient (and in most cases his or her insurer) must pay for it.

520. Brand manufacturers, including Celgene, exploit this disconnect by employing large sales forces that visit doctors' offices and persuade them to prescribe the brand manufacturers' products. These sales representatives do not advise doctors on the cost of their branded products. Studies show that doctors are typically unaware of the relative costs of brand pharmaceuticals and, even when they are aware, are largely insensitive to price differences because they do not pay for the products. The result is a marketplace where price plays a comparatively unimportant role in product selection.

521. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the own-price elasticity of demand—the extent to which unit sales go down when price goes up. This reduced-price elasticity enables brand manufacturers to raise prices substantially above marginal cost without losing enough sales to make the price increase unprofitable. The ability to profitably raise prices substantially above marginal costs is what economists and antitrust courts refer to as market power. Economists refer to monopoly power when market power rises to a level as would be held by a dominant firm. The result of these

pharmaceutical market imperfections and marketing practices is that brand manufacturers gain and maintain monopoly power with respect to many brand prescription pharmaceuticals, including Pomalyst.

522. Celgene has monopoly power in the market for Pomalyst because it has the power to exclude competition and raise or maintain the price of Pomalyst to supra-competitive levels without losing enough sales to make these prices unprofitable.

523. Celgene needs to control only brand Pomalyst, and its AB-rated generic equivalents, and no other products, in order to maintain the price of Pomalyst profitably at supra-competitive levels. Only the market entry of competing, AB-rated generic versions of Pomalyst would render Celgene unable to profitably maintain its prices for Pomalyst without losing substantial sales.

524. For years, Celgene has sold Pomalyst at prices well in excess of marginal costs and in excess of the competitive price and, therefore, Celgene had high profit margins. Celgene had, and exercised, the power to exclude generic competition to brand Pomalyst.

525. At all relevant times, Celgene was protected by high barriers to entry due to patent protection, the high cost of entry and expansion, expenditures in marketing and physician detailing, and state statutes that require prescriptions for the purchase of the products at issue and restrict substitution of those products at the pharmacy counter. The products in these markets require significant investments of time and money to design, develop, and distribute. In addition, the markets require government approvals to enter and/or the drugs at issue may be covered by patents or other forms of intellectual property. Celgene's unlawful conduct further restricted entry. Thus, during the relevant time, existing and potential market entrants could not enter and/or expand output quickly in response to Celgene's higher prices or reduced output.

526. There is direct evidence of market power and anticompetitive effects available in this case sufficient to show Celgene's ability to control the price of Pomalyst, and to exclude relevant competitors, without the need to define the relevant antitrust markets. The direct evidence consists of, *inter alia*, the following facts: (1) generic Pomalyst would have entered the market at a much earlier date, at a substantial discount to brand Pomalyst, but for Celgene's anticompetitive conduct; (2) Celgene's gross margin on Pomalyst at all relevant times was very high; (3) Celgene never lowered the price of Pomalyst to the competitive level in response to the pricing of other brand or generic drugs; and (4) from 2013 through 2022, Celgene profitably raised the price of Pomalyst by more than 200%.

527. To the extent proof of monopoly power by defining a relevant product market is required, plaintiff alleges that the relevant antitrust market is the market for Pomalyst and its AB-rated generic equivalents.

528. The United States, the District of Columbia, and the U.S. territories constitute the relevant geographic market.

529. Celgene will have a 100% market share in the relevant market until the 2026 agreed-to entry date.

VII. EFFECT ON INTERSTATE COMMERCE

530. During the relevant time period, Celgene manufactured, sold, and shipped Pomalyst across state lines in an uninterrupted flow of interstate commerce.

531. During the relevant time period, Cigna purchased, paid for, and/or provided reimbursement for some or all of the purchase price for Pomalyst and/or pomalidomide. As a result of Celgene's illegal conduct, Cigna was compelled to purchase brand Pomalyst at supra-competitive prices.

532. During the relevant time period, the defendants used various devices to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign wire commerce. The defendants engaged in illegal activities, as charged in herein, within the flow of—and substantially affecting—interstate commerce, including in this district.

VIII. CLAIMS FOR RELIEF

COUNT ONE

VIOLATION OF 15 U.S.C. § 2
UNLAWFUL MONOPOLIZATION:
DAMAGES, DECLARATORY AND INJUNCTIVE RELIEF
(Against Defendants Celgene and Bristol Myers)

533. Cigna hereby repeats and incorporates by reference each preceding paragraph as though fully set forth herein.

534. At all relevant times, Celgene (and subsequently Celgene and its new parent Bristol Myers) possessed substantial market power (*i.e.*, monopoly power) in the relevant market. Celgene, and later Celgene and Bristol Myers, possessed the power to control prices in, prevent prices from falling in, and exclude competitors from, the relevant market.

535. Through the overarching anticompetitive scheme, as alleged above, Celgene and Bristol Myers willfully maintained monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen or a historic accident, and thereby injured Cigna. Celgene's and Bristol Myers' anticompetitive conduct was done with the specific intent to maintain a monopoly in the market for brand and generic Pomalyst in the United States.

536. Celgene and Bristol Myers accomplished their scheme by entering into unlawful agreements for delay in generic entry. They did so to lengthen the period in which Celgene's

brand Pomalyst could monopolize the market, enabling Celgene and Bristol Myers to make supra-competitive profits.

537. Had Celgene and Bristol Myers competed on the merits instead of unlawfully maintaining a monopoly in the market for Pomalyst, one or more generic equivalents would have been available as early as October 30, 2020. Cigna would have substituted lower-priced generic Pomalyst for the higher-priced brand-name Pomalyst for some or all of their Pomalyst requirements and would have paid substantially lower prices for brand-name Pomalyst and generic Pomalyst.

538. The goal, purpose, and effect of Celgene's and Bristol Myers' overarching anticompetitive scheme was to block generic drugs from entering the market for Pomalyst, extend their dominance in that market, and maintain Pomalyst's prices at supra-competitive levels. The scheme has had the further effect of depriving the market of competition.

539. Celgene's and Bristol Myers' scheme substantially harmed competition in the relevant market and was an unreasonable restraint of trade.

540. There is and was no non-pretextual, procompetitive justification for Celgene's or Bristol Myers' actions that outweighs the scheme's harmful effects. Even if there were some conceivable justifications that Celgene or Bristol Myers could assert, the scheme is and was broader than necessary to achieve such a purpose.

541. But for Celgene's and Bristol Myers' illegal conduct, competitors would have begun marketing generic versions of Pomalyst beginning as early as October 30, 2020. Plaintiff's allegations comprise a violation of Section 2 of the Sherman Act.

542. Cigna has been injured in its business or property by reason of Defendants' antitrust violations. Its injury consists of having paid and continuing to pay higher prices for Pomalyst directly from Celgene and Bristol Myers, than it would have paid in the absence of

Celgene's and Bristol Myers' violations. Such overcharges are the type of injury the antitrust laws were designed to prevent and flows from that which makes Celgene's and Bristol Myers' acts unlawful.

543. Even after generic competition begins, Cigna and its subsidiaries will continue to pay supra-competitive prices for generic versions of Pomalyst until the market achieves equilibrium.

544. Cigna seeks treble damages under Section 4 of the Clayton Act, 15 U.S.C. § 15, for its direct purchases from Celgene and Bristol Myers of Pomalyst, and for Cigna's overpayments for generic Pomalyst, if and when it belatedly becomes available.

545. As a direct result of Defendants' violation of 15 U.S.C. § 2, Cigna has been injured. Additionally, pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. § 2201(a), Cigna seeks a declaratory judgment that Celgene's and Bristol Myers' conduct in seeking to prevent competition as described in the preceding paragraphs violates Section 2 of the Sherman Act.

546. Pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, Cigna further seeks equitable and injunctive relief to correct for the anticompetitive market effects caused by Celgene's and Bristol Myers' unlawful conduct and to assure that similar anticompetitive conduct does not occur in the future.

DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff respectfully demands that this Court:

A. Enter joint and several judgments against the Defendants and in favor of Cigna;

B. Award Cigna treble damages (*i.e.*, three times overcharges) in an amount to be determined at trial;

C. Grant permanent injunctive relief pursuant to § 16 of the Clayton Act to remedy the ongoing anticompetitive effects of Celgene's and Bristol Myers' unlawful conduct;

D. Award Cigna its costs of suit, including reasonable attorneys' fees as provided by law; and

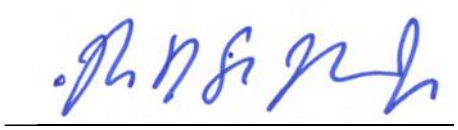
E. Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Cigna demands a trial by jury on all issues so triable.

Dated: June 24, 2025

Respectfully submitted,



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APPENDIX A

A. Celgene's asserted Revlimid patent portfolio.

1. Celgene filed for and obtained approximately thirty patents that it asserted would be infringed by various generic manufacturers' ANDAs for generic Revlimid. None of the patents for Revlimid received any exclusivities (e.g., pediatric) that would have extended exclusivity beyond the relevant patent expiration dates listed below.

2. Celgene's patents are grouped into four patent families: the '517 family of patents, REMS patents, Method of Treatment patents, and Crystal Form patents.

1. The '517 family of patents claims the pharmaceutical compound and methods of using Revlimid.

3. The '517 family of patents claims priority to U.S. Patent Application No. 08/690,258, which Celgene filed on July 24, 1996. The patents in the '517 family include the following patents that Celgene and/or Bristol Myers requested be listed in the Orange Book as covering Revlimid:

Table 2. The '517 Patent Family: Patents listed in the Orange Book

US Patent No.	Application Date	Issue Date	Expiry Date
5,635,517	July 24, 1996	June 3, 1997	Oct. 4, 2019
6,281,230	Apr. 6, 2000	Aug. 28, 2001	July 24, 2016
6,555,554	Feb. 12, 2001	Apr. 29, 2003	July 24, 2016
7,119,106	Jan. 6, 2003	Oct. 10, 2006	July 24, 2016
8,288,415	Dec. 10, 2009	Oct. 16, 2006	July 24, 2016

4. The '517 family of patents includes Orange Book-listed patents that claim methods of treating cancers with Revlimid ('230, '554, '106, and '415 patents), pharmaceutical compositions ('230, '554, '106, '415), and the pharmaceutical compound for Revlimid ('517,

claim 10). The '517 patent also claimed methods of reducing undesirable levels of TNFα in a mammal.

5. The patents in the '517 family were set to expire on July 24, 2016, with the exception of the '517 patent, which received patent term adjustments pursuant to 35 U.S.C. § 154(b).

2. The '501 REMS and '720 REMS families of patents claim methods of distributing a drug.

6. The '501 family of patents all claim priority to U.S. Patent Application No. 09/143,569, which Celgene filed on Aug. 28, 1998. The '720 family of patents all claim priority to U.S. Patent Application No. 09/694,217, which Celgene filed on October 23, 2000.

7. The '501 family of patents are all titled, "method for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug"; the '720 family of patents are all titled, "methods for delivering a drug to a patient while avoiding the occurrence of an adverse side effect known or suspected of being caused by the drug" (together, here, the "REMS patents").

8. The patents in the '501 family include the following patents that Celgene and/or Bristol Myers requested be listed in the Orange Book as covering Revlimid:[230]

[230] The '501 family also includes United States Patent No. 7,767,326, also claiming priority to Application No. 09/143,569, and which issued on July 27, 2004, and expired on Aug. 28, 2018. The '326 patent claims methods for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug. Celgene did not list the '326 patent in the Orange Book and has not asserted this patent against any ANDA applicant for generic Revlimid. When Natco asserted a counterclaim for invalidity of the '326 patent, Celgene offered, and the parties executed, a covenant to sue. 2:10-cv-5107 (D.N.J.), ECF No. 24.

Table 3. The '501 Patent Family: Patents listed in the Orange Book

US Patent No.	Application Date	Issue Date	Expiry Date
6,045,501	Aug. 28, 1998	Apr. 4, 2000	Aug. 28, 2018
6,561,976	Sep. 26, 2001	May 13, 2003	Aug. 28, 2018
6,908,432	Jan. 22, 2004	June 21, 2005	Aug. 28, 2018
8,204,763	Dec. 13, 2010	June 19, 2012	Aug. 28, 2018
8,589,188	May 17, 2012	Nov. 19, 2013	Aug. 28, 2018

9. The patents in the '720 family include the following patents that Celgene and/or Bristol Myers requested be listed in the Orange Book as covering Revlimid:

Table 4. The '720 Patent Family: Patents listed in the Orange Book

US Patent No.	Application Date	Issue Date	Expiry Date
6,315,720	Oct. 23, 2000	Nov. 13, 2001	Oct. 23, 2020
6,561,977	Sep. 27, 2001	May 13, 2003	Oct. 23, 2020
6,755,784	Mar. 7, 2003	June 29, 2004	Oct. 23, 2020
8,315,886	Dec. 13, 2010	Nov. 20, 2012	Oct. 23, 2020
8,626,531	Aug. 22, 2012	Jan. 7, 2014	Oct. 23, 2020

10. These patents were not eligible for Orange Book listing because they do not claim a drug substance (active ingredient), drug product, or method of use. Celgene nevertheless submitted the '501 and '720 families of patents to the FDA for listing in the Orange Book.

3. The '740 and '569 family of patents claim methods of treating myelodysplastic syndrome and multiple myeloma.

11. The '740 family of patents all claim priority to U.S. Patent Application No. 10/411,649, which Celgene filed on April 11, 2003. The '740 family of patents are all related to the use of Revlimid to treat myelodysplastic syndromes.

12. The '569 family of patents all claim priority to U.S. Patent Application No. 10/438,213, which Celgene filed on May 15, 2003. The '569 family of patents are related to the use of Revlimid to treat (1) multiple myeloma ("MM") and (2) various lymphomas.

13. The patents in the '740 family include the following patents that Celgene and/or Bristol Myers requested be listed in the Orange Book as covering Revlimid:

Table 5. The '740 Patent Family: Patents listed in the Orange Book

US Patent No.	Application Date	Issue Date	Expiry Date
7,189,740	Apr. 11, 2003	Mar. 13, 2007	Apr. 11, 2023
8,404,717	Mar. 24, 2011	Mar. 26, 2013	Apr. 11, 2023
9,056,120	Mar. 13, 2013	June 16, 2015	Apr. 11, 2023

14. The patents in the '569 family include the following MM patents that Celgene and/or Bristol Myers requested be listed in the Orange Book as covering Revlimid:

Table 6. The '569 Patent Family: Patents listed in the Orange Book

US Patent No.	Application Date	Issue Date	Expiry Date
7,968,569	May 15, 2003	June 28, 2011	Oct. 7, 2023
8,530,498	Apr. 8, 2013	Sep. 10, 2013	May 15, 2023
8,648,095	June 5, 2012	Feb. 11, 2014	May 15, 2023
9,101,621	Apr. 17, 2014	Aug. 11, 2015	May 15, 2023
9,101,622	Sep. 10, 2014	Aug. 11, 2015	May 15, 2023

15. The patents in the '740 family were set to expire on April 11, 2023, and the MM patents in the '569 family were set to expire on May 15, 2023, with the exception of the '569 patent, which received patent term adjustments pursuant to 35 U.S.C. § 154(b).

4. The '800 family claims crystal forms of lenalidomide.

16. The '800 family of patents all claim priority to U.S. Patent Application No. 10/934,863, which Celgene filed on September 3, 2004. The '800 family of patents are all entitled, "polymorphic forms of [lenalidomide]" (here, "crystal form patents"). These patents describe eight crystalline forms of lenalidomide, each of which is assigned a letter for identification, i.e., Form A lenalidomide through Form H lenalidomide. The various crystalline forms of lenalidomide are differentiated by the x-ray powder diffraction (XRPD) pattern, infrared (IR) spectrum, and thermogravimetric analysis (TGA) curve associated with each form.

17. The patents in the '800 family include the following patents that Celgene and/or Bristol Myers maintained would be infringed by generic ANDAs. Celgene asserted that the '800 and '217 patents covered Revlimid and asserted these patents in litigations against every ANDA filer. Celgene asserted that eleven generics' ANDAs would infringe the unlisted crystal form patents:

Table 7. The '800 Patent Family: Patents asserted in Litigation

US Patent No.	Application Date	Issue Date	Expiry Date
Listed in the Orange Book			
7,465,800	Sep. 3, 2004	Dec. 16, 2008	April 27, 2027
7,855,217	Dec. 15, 2008	Dec. 21, 2010	Nov. 24, 2024
NOT Listed in the Orange Book			
7,977,357	July 23, 2008	July 12, 2011	Jan. 8, 2025
8,193,219	Oct. 3, 2011	June 05, 2012	Sep. 3, 2024
8,431,598	May 26, 2011	Apr. 30, 2013	Sep. 3, 2024

18. The patents in the '800 family were set to expire on Sep. 3, 2024, with the exception of the '800, '217, and '357 patents, which received patent term adjustments pursuant to 35 U.S.C. § 154(b).

B. 2010–2015: Natco challenges Celgene's Revlimid patents.

19. On February 2, 2010, Natco filed ANDA No. 201452 seeking approval to sell lenalidomide capsules in 5mg, 10mg, 15mg, and 25mg strengths. FDA accepted Natco's ANDA for filing on July 12, 2010.

20. On August 27, 2010, Natco sent Celgene a paragraph IV certification challenging the claims of certain of the '517 family patents, REMS patents, and crystal patents as invalid, unenforceable, and/or not infringed by Natco's generic version of Revlimid.[231]

21. On October 8, 2010, Celgene sued Natco in the United States District Court for the District of New Jersey, Civil Action No. 2:10-05197, alleging infringement of its patents.[232] Celgene later amended its complaint to add Arrow and Watson as defendants (together with Natco, the "Natco Patent Defendants").[233]

22. Celgene's suit, filed within 45 days of receiving Natco's paragraph IV certification, triggered the Hatch-Waxman Act's automatic 30-month stay of FDA approval of Natco's generic product. This stay prevented the FDA from granting final approval of Natco's

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[231] These were the '517 (claim 10), '554, '106, '501, '720, '976, '977, '784, '432, and '800 patents. Natco also, at that time, provided section viii carveouts stating it did not seek approval for the indication covered by claims 1–9 of the '517 patent, the '230 patent, and the '740 patent, which covered methods of treatment of myelodysplastic syndromes.

[232] On January 20, 2011, Celgene agreed not to sue Natco for infringement of the '326 and '432 patents based on its filing of ANDA No. 201452 (ECF No. 24).

[233] On January 7 (ECF No. 16) and March 25, 2011 (ECF No. 53), respectively.

ANDA until the earlier of: (i) the expiration of the 30-month stay[234] or (ii) entry of a final judgment that the patents at issue were invalid, unenforceable, and/or not infringed.

23. In total, Celgene filed five amended complaints in the 2:10-cv-5197 action, another complaint in Civil Action No. 2:12-cv-4571 (subsequently consolidated with the 2:10-cv-5197 action), and another complaint in Civil Action No. 2:14-cv-3126. The Natco Patent Defendants timely answered and filed counterclaims, alleging that all the asserted patents were invalid, unenforceable, and/or uninfringed.[235]

24. At times during its ANDA review, Natco carved out certain indications by certifying to the FDA under Section 505(j)(2)(A)(viii) that the labeling for its proposed lenalidomide capsules (5 mg, 10 mg, 15 mg, and 25 mg) did not include any method of use that was claimed by certain patents (a "section viii carveout"). But by the time the parties began negotiating a settlement in May 2015, Natco was seeking approval of a label that included the RLD-approved indications for treating multiple myeloma and myelodysplastic syndromes and carved out the only then-approved indication for treating mantle cell lymphoma. Celgene never

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[234] Celgene's ANDA was the subject of two 30-months stays. The second, based on a later paragraph IV certification, expired on December 12, 2014.

[235] In their January 14, 2011 Answer, the Natco Patent Defendants also asserted counterclaims for invalidity and inequitable conduct as to two related but unasserted REMS patents ('432 and '326 patents) on behalf of themselves as well as Counterclaim Plaintiffs Watson, Actavis, Inc., and Anda, Inc. (related entities that Celgene had initially refused to include in a covenant not to sue which was then being negotiated). 2:10-cv-5197, ECF No. 18. After the parties executed a covenant not to sue on these patents that included Watson, Actavis, and Anda, ECF No. 24, on February 25, 2011, Counterclaim Plaintiffs Watson, Actavis, and Anda voluntarily dismissed their claims without prejudice to Natco Patent Defendants' continued assertion of the counterclaims. ECF No. 41.

On May 15, 2014, Celgene temporarily added Anda, Actavis, and Watson as defendants in a new action before dismissing the entities on June 16, 2014. *See Celgene v. Natco Pharm.,* No. 2:14-cv-3126 (D.N.J.), ECF Nos. 1, 11.

sued Natco for infringement of patents related to the treatment of mantle cell lymphoma (the '363 and '929 patents).[236]

25. Over a period of about five years—from when the first lawsuit was filed in 2010 to an eventual settlement in 2015—Natco took the position that Celgene's patents did not prevent it from coming to market, and Celgene disagreed, claiming that its patents prevented Natco from coming to market until the expiration of the last asserted patent on April 27, 2027.

26. Ultimately, the parties negotiated an agreement that resolved the litigation. The negotiation began around May of 2015 and the agreement (discussed further below in Section V.I.) was finalized on December 22, 2015.

27. By May 2015: (i) Celgene had agreed not to sue Natco for infringement of the '326, '432, '217 and '763 patents;[237] (ii) the parties had stipulated to the dismissal of claims relating to the '230, '554, '106, and '415 patents because Natco had submitted a paragraph III certification that it was no longer seeking approval of its ANDA prior to the latest of the expirations of those patents on July 24, 2016;[238] (iii) the parties had stipulated that Natco's ANDA product would infringe the '501, '720, '976, '977, '784, and '886 (REMS) patents, without

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[236] On July 20, 2018—after the Celgene-Allergan agreement—Natco submitted newly proposed labeling that added the RLD-approved indication for treatment of MCL and also amended its ANDA to seek approval to market 2.5mg and 20mg strengths of its generic lenalidomide. Natco carved out other later-approved RLD indications for the treatment of multiple myelomas maintenance following autologous hematopoietic stem cell transplantation (auto-HSCT), as well as the RLD-approved indications for the treatment of marginal zone lymphoma and follicular lymphoma. Teva (after transfer from Natco) ultimately obtained FDA approval and launched with a label containing all strengths featuring the MDS, MCL, and the MM indication (but carving out maintenance following auto-HSCT).

[237] 2:10-cv-5197, ECF No. 24 (as to '326 and '432); 2:10-cv-5197, ECF No. 145 and 2:12-cv-4571, ECF No. 14 (as to '763); 2:10-cv-5197, ECF No. 140 and 2:12-cv-4571, ECF No. 8 (as to "217).

[238] 2:10-cv-5197, ECF No. 402.

limiting Natco's ability to challenge the validity of the asserted claims in those patents,[239] but then the Court granted Celgene's motion to bifurcate and stay discovery related to those patents anyway;[240] and (iv) the parties had agreed to temporarily bifurcate and stay discovery related to the '188 and '531 (REMS) patents.

28. Thus, Natco was actively asserting invalidity and non-infringement as to the '517, '740, '717, '569, '800, '357, '219, '598, '498, and '095 patents; Natco also had arguments as to the '188 and '531 patents and invalidity arguments as to the '501, '720, '976, '977, '784, and '886 patents, but discovery had been stayed as to those patents. The court issued a Markman opinion adopting Natco's construction of the '598 and '357 patents and adopting Celgene's construction of the '800 patent.[241] The construction of the '800 patent opened up new invalidity arguments for Natco, which it asserted after the Court granted it leave to amend its contentions.[242] The parties had served opening expert reports in April 2015, and would serve responding expert reports in September 2015, but did not serve reply expert reports before settling.

[239] 2:10-cv-5197, ECF No. 305.

[240] 2:10-cv-5197, ECF No. 358.

[241] 2:10-cv-5197, ECF No. 312; 2:10-cv-5197, ECF No. 313.

[242] 2:10-cv-5197, ECF No. 366.